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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

In re CONNETICS SECURITIES LITIGATION	Case No. C 07-02940 SI **CLASS ACTION** **LEAD PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS THE SECOND AMENDED CONSOLIDATED COMPLAINT** Date: August 15, 2008 Time: 9:00 a.m. Courtroom: 10 Judge: Hon. Susan Illston

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STATUTES

The Teachers' Retirement System of Oklahoma (the "Lead Plaintiff") respectfully submits this Memorandum in opposition to the separate motions to dismiss [Doc. Nos. 94, 96, 104] filed by Defendants Connetics Corp. ("Connetics" or the "Company"), John Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas Wiggans (the "Connetics MTD") and the motion to dismiss filed by Alexander Yaroshinsky (the "Yaroshinsky MTD"), and to the motion filed by Victor Zak, who joins in the Connetics MTD and the Yaroshinsky MTD.

I. INTRODUCTION

This is a securities fraud class action on behalf of purchases of the securities of Connetics Corp. between January 27, 2004 and July 9, 2006 (the "Class Period"). The Second Amended Consolidated Class Action Complaint (the "Complaint") cures the pleading deficiencies identified in the Court's January 29, 2008 Order (the "1/29 Order" [Doc. No. 83]) and otherwise meets Ninth Circuit pleading standards.

Connetics is a pharmaceutical company that markets dermatological products. Knowing that Velac Gel, a potential new acne medication, had failed the preclinical test that the FDA required before it would allow Connetics to sell the drug, Defendants' concealed the results of the test and continued to promote the timely approval and release of Velac. In accordance with the Court's prior Order, the Complaint alleges facts to demonstrate the investigation and basis for the Complaint's allegations – including, for example, Defendants' own admissions, sworn declarations from counsel in *United States Securities and Exchange Commission v. Yaroshinsky* and corroborating interviews with percipient witnesses.[1]

The Complaint alleges that Velac depended on a novel new vehicle (¶¶69-72), that the FDA set a deadline of June 25, 2005 – known as the "PDUFA date" – for ruling on Connetics' drug application (¶¶66-67), and that Velac's failure in required preclinical tests prevented approval by the PDUFA date if ever. ¶¶97-99. Delayed approval of Velac diminished Connetics' ability to capture the acne treatment market before its competitor, Medicis. *See, e.g.*,

[1] *See* ¶¶42-61. In addition, Lead Plaintiff respectfully refers the Court to the accompanying Memorandum of Law In Opposition to Defendants' Motions to Strike Facts Alleged In the Second Amended Complaint.

Warshaw v. Xoma Corp., 74 F.3d 955 (9th Cir. 1996) (reversing dismissal where defendants "knew during th[e] course of events that there was no chance for timely FDA approval").

In their motions, Defendants attempt to dispute the strong inference of scienter by urging the Court to assume that they knew of purportedly similar drugs with the same results as Velac in Tg.AC mouse studies that eventually obtained FDA approval. Connetics MTD at 8-9, 16. There is no basis for such an assumption. In truth, Defendants' own expert panel expressly informed Defendants that they knew of no drug exhibiting Velac's results that had ever been approved by the FDA, and Connetics' own liason with the FDA confirmed that the FDA would not approve any drug that tested positively without additional pre-approval animal testing. ¶¶94, 97-98. Moreover, Defendants' simply mischaracterize the Complaint. The Complaint alleges that Defendants were aware by June 2004 that, at a minimum, approval would be delayed due to additional time-consuming tests. ¶¶96-99. Consequently, Defendants' *post hoc* reliance on labels for a few different drugs says nothing about their state of mind concerning Velac's approval by the PDUFA date.

Moreover, after April 13, 2005, when the FDA's Executive Carcinogenicity Assessment Committee ("ECAC") told Connetics what its own expert panel had told them in June 2004 – that the "positive dermal" experienced in the Mouse Study was a serious impediment to FDA approval of Velac – "[D]efendants had an obligation to disclose to investors the significant and material information regarding the FDA's statement that the possible carcinogenic effect of Velac was a 'serious issue.'" 1/29 Order at p. 17. Nevertheless, on April 14, Defendants hosted an analyst day and continued to make positive statements about Velac and its release. ¶¶111-115.

In addition, there is no dispute that Connetics issued false financial statements. By restating financial results after the Class Period, "defendants admit that their financial statements were misstated with regard to reserves." 1/29 Order at 19. Beginning with the earnings release on January 27, 2004, Defendants inflated the Company's reported earnings by "selling" to its wholesale distributors excessive amounts of its existing products, while Defendants expressly assured investors that they monitored and maintained accurate distributor inventory levels and properly reserved for returns of products sold to distributors. The restatement, together with the

additional allegations in the Complaint, provide ample particularity and raises a strong inference of scienter – including the products, the main wholesalers, the specific provisions of GAAP, the periods at issue, the amounts restated and defendants' roles in monitoring inventory levels and shipping excess product. ¶¶148-205.

In short, the Complaint is a well-pled document, based on an independent investigation, that addresses the prior pleading deficiencies. It alleges Defendants' fraud and insider trading in detail, and Lead Plaintiff respectfully submits that their motions to dismiss should be denied.

II. SUMMARY OF THE COMPLAINT'S ALLEGATIONS

The Complaint asserts claims for defendants' violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b). The Complaint alleges in detail how Connetics and the Insider Defendants issued false and misleading statements that inflated the price of Connetics' securities.[2] The inflation was later removed through a series of partial disclosures until the final disclosure on July 10, 2006. ¶343. Further, the Complaint alleges that Defendants Yaroshinsky, Zak, Wiggans, Higgins, and Vontz (the "§ 20A Defendants") are liable under § 20A of the Exchange Act, 15 U.S.C. § 78t-1, for selling their own shares while in possession of material, non-public information. ¶¶328-332.

A. Defendants Concealed Velac's Failure In Preclinical Tests

To market its dermatological products, Connetics had to obtain FDA approval. ¶¶62, 65. The Prescription Drug User Fee Act ("PDUFA") requires that the FDA give pharmaceutical companies a date certain for the FDA's determination on New Drug Applications (or NDAs). ¶66. Velac had a PDUFA date of June 25, 2005. ¶67.

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[2] "Insider Defendants" refers to Wiggans (Connetics' Chief Executive Officer), Vontz (Executive Vice President and Chief Commercial Officer, Chief Operating Officer and President), Higgins (Chief Financial Officer and Executive Vice President, Finance and Administration and Corporate Development), and Krochmal (Executive Vice President of Research and Product Development). ¶¶34-39. Yaroshinsky served as Vice President of Biostatics and Clinical Operations for Connetics during the Class Period and was responsible for analyzing the results of drug development studies and preparing regulatory submissions to the FDA – including Velac. ¶¶40, 90. At all relevant times, he was an employee of Connetics and his knowledge is attributed to the Company. *See In re CV Therapeutics, Inc. Sec. Litig.*, 2004 WL 1753251, at *10 (N.D. Cal. Aug. 5, 2004).

Even though Velac was a combination of two previously-FDA-approved drugs – clindamycin and tretinoin – Connetics was required to obtain independent FDA approval of Velac. ¶¶68-70. Importantly, Velac contained a novel "vehicle" (the base in which the active ingredients are stored and delivered) that was critical to the development of Velac because it allowed clindamycin and tretinoin to be combined in an unprecedented manner. ¶¶69-72. The vehicle itself had to be proven safe before Velac could be approved by the FDA. ¶72.

Beginning in the second half of 2003 or early 2004, BioReliance performed a Tg.AC mouse dermal carcinogenicity study on Velac (the "Mouse Study"). ¶88. This Mouse Study, required by the FDA, was designed to determine whether Velac had any carcinogenic effects. Shortly after testing began, according to a former employee in Connetics Strategic Market Planning group ("CW4"), Connetics' Executive Committee held a meeting attended by, among others, Defendants Vontz, Higgins, and Wiggans, as well as Jay Finister (Senior VP of Marketing), Danine Summers (VP of Marketing), Dr. Xinfan Huang (Director of Pharmacology and Toxicology and lead pre-clinical scientist for the Mouse Study), during which Dr. Huang gave a presentation concerning the high incidences of tumors in the Mouse Study. ¶¶43(d), 91. By no later than mid-June 2004, Defendants knew 89 out of 160 of the mice in the Mouse Study (56%) developed skin tumors. Velac was potentially a tumor promoter or carcinogen. ¶93. On June 28, 2004, Connetics convened a panel of toxicology experts (the "Toxicology Panel" or "Panel"). The Panel informed Connetics that it knew of no drug that exhibited a "positive dermal" similar to Velac's results that ever had been approved by the FDA. ¶94.

As a result of the positive Mouse Study results, Defendants knew no later than June 2004 that it was extremely unlikely that Velac would be approved prior to the PDUFA date. According to a recognized expert in use of the Tg.AC mouse study who served on the Toxicology Panel ("CW5"), if more than 20% of the mice in a Tg.AC study develop tumors the FDA requires further testing and will not approve that drug without first obtaining the results of the additional testing. ¶¶96-97. Velac caused tumors in 56% of mice, thereby necessitating lengthy additional testing. Similarly, according to a former Connetics Senior Manager of Regulatory Affairs who handled Connetics' communications with the FDA ("CW6"), once

Connetics learned the results of the Tg.AC Mouse Study, there was nothing the Company could do to prove Velac was safe other than a two year CARC study. ¶98. Because the Company, at the very least, had to perform additional carcinogenicity testing in order to obtain FDA approval, Defendants knew approval by the PDUFA date was extremely unlikely. ¶99.

Even after June 2004, Defendants continued to promote Velac's prospects for approval by the FDA and even included revenue from Velac in guidance. ¶101. Without mentioning the failed Mouse Study, Defendants continued to tell the market Velac was "safe" and "express confidence in the product's timing," causing analysts to believe Velac would begin generating millions of dollars of revenues for the Company by the second half of 2005. ¶¶102-105. *See also* ¶250 (Form 10-K stating "The data from these trials also demonstrated that Velac was safe. . . ."), ¶252 ("the Company has high confidence in an outright FDA approval by June 25th 2005").

On April 13, 2005, Connetics held a private conference call with members of the FDA's ECAC for the purpose of discussing the FDA's comments and conclusions on the NDA for Velac (the "ECAC Conference Call"). ¶107. The FDA told Connetics what the Toxicology Panel had said on June 28, 2004 – namely, that the "positive dermal" experienced in the Mouse Study was a serious impediment to FDA approval of Velac. ¶108. Recognizing that a formal FDA non-approval letter was imminent, on the day after the ECAC Conference Call, Connetics attempted to prohibit employees from trading in the Company's securities. ¶110.

On April 14, 2005, Connetics hosted their annual 2005 Analyst and Investor Day – during which Defendants made favorable presentations concerning Velac. ¶¶111-112. Moreover, Defendants increased the Company's 2005 revenue guidance, which included revenues from Velac sales in 2005, thereby telling investors the Company still expected FDA approval by the PDUFA date. ¶112. *See also* ¶254. Despite having just been told by the FDA's ECAC that Velac was not likely to be approved, Defendants misled analysts and investors into believing the Company was "confident in approval" of Velac by June 25, 2005, and that Connetics was "on the verge of launching" Velac with "FDA approval anticipated." ¶¶113-114. *See also* ¶¶255-258. As a result, the Company's stock price increased by nine percent in the days after the ECAC Conference Call. ¶115.

After the market closed on April 26, 2005, two weeks after the ECAC Conference Call, Connetics issued a press release stating that the FDA was interpreting the Mouse Study results differently than the Company had. ¶116. This partial disclosure of the truth concerning Velac caused Connetics shares to decline 17% in one day. ¶126. However, Defendants did not disclose that they knew it was extremely unlikely Velac would be approved by the PDUFA date. Rather, Defendants assured investors that Connetics had "carefully analyzed the results [of the Mouse Study] with a panel of leading toxicologists and experts in this model" and that positive test results were merely a "result of a limitation of the model." ¶117. Defendants falsely reassured investors the Company was "working with the FDA . . . so this issue can be resolved and enable us to launch Velac on schedule." ¶120. *See also* ¶264 ("We are, of course, forecasting the launch of Velac in the third quarter at this time with this guidance."). In truth, the Company could not obtain FDA approval without first conducting additional carcinogenicity animal testing – which could not be done before the PDUFA date of June 25, 2005. ¶121.

Furthermore, on April 26, Defendants misled investors and analysts by reassuring them that Velac's test results were similar to those of benzoyle peroxide, a commonly used acne medication, and falsely telling the market that "only one mouse" developed skin tumors in the Tg.AC mouse testing of Velac. ¶¶120, 263, 266. These statements were false and misleading. There is no basis from which to believe Velac's test results were similar to those of BenzaClin/benzoyl peroxide. ¶¶121-125. And, as Defendants knew, Velac caused tumors in 89 of 160 mice in the study – not just one mouse. ¶92.

On April 27, 2005, following the Insider Defendants' false and misleading statements on April 26 concerning the FDA's comments about Velac, Defendant Yaroshinsky sold nearly all his Connetics common stock and purchased 41 put contracts in order to profit from a collapse in Connetics stock. ¶137. Defendant Yaroshinsky continued to aggressively bet massive amounts of money against Connetics stock until June 10, 2005. ¶¶138-139.

On Monday, June 13, 2005, before the market opened, Connetics disclosed that the FDA had not approved Velac because of the "positive carcinogenicity signal that was detected in a Tg.AC mouse dermal carcinogenicity study." ¶129. On this news, Connetics stock dropped

27% on heavy trading volume. ¶132.

B. Yaroshinsky And Zak's Illegal Insider Selling

On April 13, 2005, shortly after the ECAC Conference Call, Defendant Yaroshinsky telephoned his friend and former neighbor, Defendant Zak, at Zak's office in Connecticut and told him that FDA approval of Velac was not likely. ¶133. Defendant Zak immediately short sold Connetics shares and continued to do so (and buy put contracts) between April 14, 2005 and June 10, 2005, in order to profit when Connetics' stock declined. ¶134. On April 14, 2005, the day Connetics instituted a trading ban for certain of its employees, including Yaroshinsky, Yaroshinsky opened a nominee brokerage account in the name of his mother-in-law that he funded and controlled. On April 21, 2005, before the Company's trading ban expired, Defendant Yaroshinsky purchased 5 put contracts in the nominee account under the name of his mother-in-law. ¶136.

C. The Admittedly False Financial Statements

During the Class Period, Connetics primarily sold its products to three large distributors, Cardinal Health, McKesson, and AmerisourceBergen, who placed the products in inventory for subsequent sale into the retail marketplace. ¶¶149, 151. Typically, the end-users of Connetics' products would fill their prescriptions at retail pharmacies that purchase their prescription medication from the large distributors. ¶151. When Connetics sold products to its distributors, those sales were subject to certain conditions. ¶151. For instance, distributors' excess inventory that approached expiration could be returned to Connetics for a refund; this refund could exceed the initial sale price of the drug. ¶¶154, 168.[3] Despite these conditions on Connetics' sales to distributors, Connetics booked revenue on product sold to distributors at the time of shipment. ¶155. Accordingly, accounting rules and contracts required that Connetics closely monitor the levels of its distributors' inventories and not ship more product to distributors than was necessary

[3] The Company would later admit it had improperly calculated reserves "using the original sales price" of the drug and that "price increases [after] the date of sale" caused these reserves to be understated in error, requiring the Company to restate its financial results. ¶188. The Company further admitted it had not properly considered "all units with potential risk of return" in calculating its reserve for returns. ¶189.

to satisfy end-users' needs. ¶¶155-162, 164. Indeed, Defendants repeatedly assured investors that the Company closely monitored its distributors' inventory levels "using a combination of techniques." ¶158. Connetics did so by "tracking the prescriptions filled for our products at the pharmacy level" based on information provided by independent third parties. ¶¶158-159. Moreover, the Company supposedly "tr[ied] to maintain inventory levels that are no greater than necessary to meet our current projections." ¶162.

In truth, however, Defendants caused Connetics to repeatedly ship excess product to distributors so that Connetics could improperly record income from these "sales" and artificially inflate the Company's publicly reported earnings. For instance, according to Confidential Witness 3 ("CW3"), a National Account Director in charge of Sales Operations, Defendants Wiggans and Vontz were repeatedly told during the Class Period that the amounts of product being shipped greatly exceeded the number of prescriptions written – yet Wiggans, Higgins and Vontz repeatedly directed employees to ship more product to distributors to meet Wall Street's financial projections. ¶¶166, 171. A former Senior Vice President in sales (CW7), a former territory manager (CW8), a former Vice President in sales (CW9), and a former Regional Sales Director (CW10) corroborate CW3's account. ¶¶172-173.

This case is not merely about improper channel-stuffing. Defendants made false and misleading statements specifically assuring investors that distributors' inventory levels were not inflated. ¶¶157-162, 248, 275-276. Moreover, Defendants falsified the Company's financial results by not taking required reserves to account for all the product returns, rebates and chargebacks caused by their insistence on injecting excessive inventory into the distribution channel. ¶175. Shipping more product to the distributors than the distributors could sell to end-users could not continue indefinitely. ¶176. As Connetics' drugs (specifically Soriatane, OLUX Foam, Evoclin Foam, and Luxiq Foam) languished at distributors, the inventory got older and the risk of return of larger amounts of expired or nearly-expired product increased, requiring the Company to slash shipments to distributors at the end of 2005 and in the beginning of 2006. ¶176.

The Company was forced in May 2006 to announce its financial statements were false. ¶¶176-177. According to a former National Account Director in charge of Sales Operations, the Company's announcement was not a surprise to anyone at Connetics because "the numbers have never been real from day one" and the Company was "not honest with the public." ¶167.

In July, the Company revealed that its then-current financial results were far below expectations because the Company had to reduce inventory levels at its distributors. ¶182. The Company reduced shipments to distributors for the remainder of 2006 to clear out excessive inventory of expiring Connetics' product that had been stuffed into their channels in prior reporting periods. *Id.* As a result, the Company's stock price collapsed. *See, e.g.* ¶¶182-185.

III. ARGUMENT

When considering a motion under Fed. R. Civ. P. 12(b)(6), the question is not whether a plaintiff will prevail in the action, but whether it is entitled to offer evidence in support of its claim. *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974); *Johnson v. Knowles*, 113 F.3d 1114, 1117 (9th Cir. 1997). Dismissal is proper "only when there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory." *Siaperas v. Mont. State Comp. Ins. Fund*, 480 F.3d 1001, 1003 (9th Cir. 2007). In answering this question, the Court must "accept all factual allegations in the complaint as true." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (U.S. 2007). Likewise, the court construes all allegations in the light most favorable to the non-moving party and draws all reasonable inferences in favor of the plaintiff. *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th Cir. 2005); *Wyler Summit P'ship v. Turner Broad. Sys., Inc.*, 135 F.3d 658, 661 (9th Cir. 1998). When considering the strong inference of scienter, the Court may consider plausible opposing inferences; "however, [they] may be based only on the complaint and other public documents on which Courts ordinarily rely in deciding a motion to dismiss, 'while constantly assuming the plaintiff's allegations to be true.'" *In re Scottish Re Group Sec. Litig.*, 524 F. Supp. 2d 370, 383 (S.D.N.Y. 2007) (*quoting Tellabs*, 127 S. Ct. at 2511-12); *see also Berson v. Applied Signal Tech., Inc.*, 2008 U.S. App. LEXIS 11982, at *11-14 (9th Cir. June 5, 2008)(accepting allegations as true and plaintiffs' inferences). "The Court should not use judicial notice to

generate an evidentiary record and then weigh evidence – which plaintiffs have not had the opportunity to challenge – to dismiss plaintiffs' complaint." *In re Network Equip. Tech., Inc. Litig.*, 762 F. Supp. 1359, 1363 (N.D. Cal. 1991).[4]

Rather than accept as true the well-pleaded allegations, Defendants' Motions rely upon factual assertions not found in the Complaint nor properly judicially noticed. *See, e.g.*, Connetics MTD at 4-13. For instance, Defendants attempt to compare Velac to another drug named Clobex, noting Clobex was eventually approved by the FDA "notwithstanding similar 'safety' concerns..." Connetics MTD at 11, fn. 11. In truth, however, Clobex is a possible teratogen (*see* Exhibit 42), whereas Velac is a possible carcinogen – the two are incomparable.[5] Defendants also assert that European clinical studies demonstrated Velac was safe. Connetics MTD at 6-7. But, these clinical studies are irrelevant, did not test for carcinogenicity, and it is common knowledge that carcinogenic affects in human beings may be hidden for decades. Such arguments should be reserved for the ultimate trier of fact after the record is developed.

Previously, when confronted with similar arguments at the motion to dismiss stage, this Court refused to accept defendants' invitation to weigh the evidence. For instance, in *In re CV Therapeutics Sec. Litig.*, defendants offered evidence that their statements "concerning the efficacy and safety" of a new drug had a "reasonable basis." 2004 U.S. Dist. LEXIS 17419 at *14 (N.D. Cal. Aug. 5, 2004). The Court refused to consider defendants extraneous evidence.

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[4] *See also In re NPS Pharm. Sec. Litig., Inc.*, 2007 WL 1976589, at *1 (D. Utah July 3, 2007) (striking exhibits to motion to dismiss where defendants "made misleading statements regarding the safety, efficacy, potential for FDA approval, and potential market size of [a drug] in violation of §10(b)"); *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 995 (S.D. Cal. 2005) (same); *Faulkner v. Beer*, 463 F.3d 130, 134 (2d Cir. 2006) (vacating dismissal of complaint because district court considered "materials outside the record"); *In re Applied Micro Circuits Corp. Sec. Litig.*, 2002 U.S. Dist. LEXIS 22403, at *8 (S.D. Cal. Oct. 3, 2002) (refusing to consider "extrinsic evidence").

[5] Defendants' likewise attempt to compare Velac to other drugs, but there is nothing before the Court concerning the tumor-creation rate of these other drugs from which the Court can make a reasonable comparison. Nor is there any evidence before the Court concerning whether these other drugs were approved only after subsequent carcinogenicity testing proved their safety – which Connetics had not performed on Velac. ¶¶97-99, 122-124.

Id. at *17. ("Characterizations of the allegations and evidence will need to wait for the next stage of the litigation.")

Concurrently herewith, Lead Plaintiff files its Opposition to Defendants' Request for Judicial Notice. This Opposition brief demonstrates that Defendants improperly seek "judicial notice" of SEC filings and other public documents to introduce disputed facts into the record, and then, on the basis of these disputed facts, assert that Lead Plaintiff's allegations should not be accepted as true. Under Ninth Circuit law, the Court may ***not*** take "judicial notice of disputed facts stated in public records." *Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001); *see also In re Adaptive Broadband Sec. Litig*., 2002 WL 989478, at *20 (N.D. Cal. Apr. 2, 2002) (same as to SEC filings).

A. The Complaint Complies With The PSLRA And Fed. R. Civ. P. 11

In its prior Order, the Court granted Defendant Yaroshinsky's motion to strike certain allegations on the grounds that allegations cannot be asserted on facts alleged in a complaint filed by the SEC, without independent investigation. Now, the Complaint pleads 10 pages describing Lead Plaintiff's support for its allegations and the extent of Lead Plaintiff's investigation, including fact witnesses corroborating the SEC Complaint (¶43(a)-(l)), evidence of the SEC's extensive investigation (¶48), the record in the SEC action – including defendants' answers, the court's approval of a temporary restraining order, and affidavits filed by the SEC – demonstrating the facts in the SEC Complaint are accurate (¶¶44-47, 52-55), and, Defendants' own admissions to the accuracy of many of the facts (¶¶50, 53, 56-61). *See generally*, ¶¶42-61. To avoid duplication, Lead Plaintiff respectfully refers the Court to the Complaint and to the accompanying Opposition to Defendants' Motions to Strike.

B. Defendants' Velac Fraud

1. Defendants Knowingly Misled Investors About The Likelihood Of Velac Obtaining FDA Approval By The PDUFA Date

Connetics' revenue forecasts for 2005 included Velac sales of $20 million in 2005. ¶100. If investors knew Velac could not obtain FDA approval by the PDUFA date, investors would reduce their revenue expectations causing the Company's stock price to drop. Further, Connetics

was rushing to get Velac to market before a competitor, Medicis, and therefore obtain a marketing advantage. *Id*. *See also Warshaw v. Xoma Corp.*, 74 F.3d 955 (defendants "knew . . . there was no chance ***for timely FDA approval***" and delay would "greatly diminish . . . chances of capturing the . . . market"). Indeed, according to CW6, time is money in the pharmaceutical business. ¶100.

a. By Mid-June 2004, Defendants Knew Velac Likely Would Not Obtain FDA Approval By The PDUFA Date

Defendants knew, at least as early as June of 2004, that it was extremely unlikely the FDA would approve Velac within the timeframe Defendants were telling investors. According to a former Connetics employee who was the commercial representative for Velac and was kept informed as to Velac's progress towards approval for commercial sale (and who was friends with Defendant Yaroshinksy) ("CW4"), there were clear signs that the Company would have problems getting Velac approved by the FDA. ¶91. For instance, CW4 attended an Executive Committee Meeting in late 2003 or early 2004 during which Dr. Xinfan Huang told Defendants Wiggans, Higgins, and Vontz, among others, that it was clear that there were high incidences of tumors in the mice in the study. ¶91. In June 2004, the Mouse Study results revealed that 89 of 160 mice treated with Velac developed tumors. ¶¶92-93. And, on June 28, 2004, the Company convened its own panel of experts to review the results of the Mouse Study. The Panel told Defendants that the Panel did not know of any drug that exhibited a "positive dermal" ***similar*** to Velac that ever had been approved by the FDA. ¶94. The Panel's conclusion, in-and-of-itself, notified Defendants that Velac was not likely to ever obtain FDA approval, much less to obtain approval by the PDUFA date.

Velac was not going to gain FDA approval within the timeframe that Defendants were telling the marketplace. ¶¶95-100. When mice in a Tg.AC study develop tumors in significant numbers (over 20%), the FDA will not approve that drug application without ***first*** requiring additional (and lengthy) carcinogenicity testing that proves the drug is not a carcinogen. ¶¶96-98. Velac caused tumors in far more than 20% of the mice in the Mouse Study (¶96), and since the Company had not performed additional testing showing Velac to not be a carcinogen, there

was no basis to believe FDA approval by the PDUFA date was possible. ¶99.

The FDA would not approve a drug that tested positively in a Tg.AC study without first obtaining the results of additional testing. ¶¶96-99. In this litigation, however, Defendants contend that they "were aware that the FDA had approved other acne drugs that had tested positive in the Tg.AC model (such as Benzaclin and Duac), requiring only ***post-approval*** Phase IV carcinogenicity testing and labeling." Connetics MTD at 16 (relying upon Exs. 31 and 33). Defendants' contention fails in several respects. ***First***, this argument is procedurally improper as it relies upon the submission of evidence from outside the Complaint that is not subject to judicial notice. *See supra* pages 9-11.

Second, Exhibits 31 and 33 do not stand for the proposition that Defendants cite them for. Both exhibits demonstrate that the FDA required post-approval testing of the effects of the drug on UV-induced skin cancers. However, neither exhibit supports Defendants' contention that the FDA approved these drugs without additional ***pre-approval*** carcinogenicity testing demonstrating that the drug was not a carcinogen. Such additional testing is not disclosed in a product insert. *See* ¶122.

Third, Defendants' argument in litigation is contrary to Defendants' own Class Period statements. Attempting damage control in its April 26, 2005 press release, the Company claimed that it knew of "other products which had a positive finding but were ultimately approved ***based on additional work in other animal models***." ¶117. Likewise, Defendant Wiggans admitted that such other products that "had a positive finding in this [Tg.AC] model, ***result[ed] in a clinical hold only to be released later, based upon submission of additional data***." ¶120. In other words, Defendants knew FDA approval of Velac would at least be put on clinical hold until it could be proved safe.

Fourth, Defendants' citation to FDA approval of Duac appears to be *post hoc* reasoning solely for litigation. No factual evidence appears in the record to demonstrate that Defendants relied upon the FDA approval of Duac at the time they made their false statements; indeed, Defendants did not even raise Duac in their initial motion to dismiss briefing. ***Finally***, as set forth in detail in § III.B.3.c, Defendants cannot dispute a strong inference of scienter by asserting

that they believed Velac would be approved by the PDUFA date because BenzaClin (or any other drug) tested positive in a Tg.AC mouse test. The Complaint alleges facts to show that Defendants could not legitimately compare the novel vehicle in Velac to BenzaClin and benzoyl peroxide.[6]

The eventual FDA approval of a small number of drugs that tested positively in Tg.AC mouse studies did not give Defendants a reasonable basis to reject the conclusion of their expert panel (¶94) and instead hope implausibly that Velac would be approved in a timely manner. The FDA requires carcinogenicity testing for a reason. Unless the FDA approved all drugs that test positive as carcinogens without further testing, then the only reasonable conclusion is that a positive carcinogenicity test will result in FDA denial unless additional testing demonstrates the drug is safe.

Defendants argue that any "claim of actual knowledge is also irreconcilable with the concrete business decisions Connetics made in preparation for the launch of Velac. . . . It strains credulity that defendants would . . . invest significant resources, knowing all the time that the Velac NDA was deficient and that Velac could not be approved without additional testing." Connetics MTD at 18-19. This same contention has been correctly rejected by many other courts on similar facts.[7]

The fact that the Insider Defendants spent the Company's money to pursue an extremely unlikely approval of Velac – thereby artificially inflating Connetics' stock price while the Insider Defendants sold their own shares and reaped oversized bonuses – is not at all illogical. Wiggans, Higgins and Vontz sold over $4.6 million in Connetics stock between June 15, 2004 and June 13,

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[6] ¶¶96-99, 121-126. Defendants contend "plaintiff's allegations regarding to benzoyl peroxide are arguments, not facts" (Connetics MTD at 30, fn.33), but Defendants fail to address the facts showing that comparing Velac results to benzoyl peroxide was misleading. ¶¶121-126.

[7] For example, in *In re Amylin Pharm., Inc. Sec. Litig.*, 2002 WL 31520051 (S.D. Cal. Oct. 10, 2002) *recons. denied*, 2003 WL 21500525 (S.D. Cal. May 1, 2003), the court held that though defendants "clearly ***hoped*** . . . to obtain FDA approval and undoubtedly spent significant amounts of money pursuing the trials to that end[,]" defendants could be liable because they knew of a "problem" and took a "calculated risk of continuing" to seek FDA approval but "misled Plaintiffs about such risk by making assurances regarding the completeness of the data and the likelihood of FDA approval." *Id*. at *5 (emphasis in original).

2005 when the Company revealed Velac had been denied approval – all at prices artificially inflated by Defendants' failure to disclose the truth about Velac. ¶328.

b. Defendants Made Material, Misleading Statements About The Likelihood Of FDA Approval By The PDUFA Date

As set forth above, Defendants made a number of material statements throughout the Class Period prior to April 13, 2005 concerning the likelihood of Velac obtaining FDA approval. For instance, during the Company's January 25, 2005 conference call, defendants stated, among other things: (i) "We have excellent data on Velac. . . . [W]e are confident that we will be successful in this market with our acne franchise, and in particular, with Velac" (¶241); and (ii) "Velac, we expect to be launched midyear . . . . In 2006, we forecast enjoying a full year of Velac sales." (¶242). Similarly, Defendant Higgins told analyst David G. Buck in March 2005 that "the Company has high confidence in an outright FDA approval by June 25th 2005." ¶252. These and other similar statements were misleading because, as set forth above, Defendants failed to disclose the results of the Mouse Study and the conclusions of the Toxicology Panel; in particular, Defendants failed to disclose that the Company would have to conduct additional testing to demonstrate that Velac was not a carcinogen and that this additional testing would push out FDA approval by many months if not years. ¶245.

Analysts and investors relied upon Defendants' statements concerning Velac, and were misled. For example, on September 29, 2004, an analyst from Jefferies & Company, Inc. reported: "We believe Velac gets approved with minimal obstacles and becomes a significant growth driver for Connetics on its path to becoming a leading acne therapy." ¶86. *See also* ¶252. Moreover, obtaining approval by the PDUFA date was critical to Connetics and investors. ¶100. Accordingly, Defendants' omissions – that the Toxicology Panel believed approval was highly unlikely (¶94) and that Connetics would have to conduct an additional carcinogenicity study prior to FDA approval (¶¶96-99) – were material omissions.

c. Defendants' False Statements About FDA Approval And Velac Revenues Are Not Protected By The PSLRA Safe Harbor

"A forward-looking statement qualifies for the PSLRA 'safe harbor' and is not actionable if either of the following two conditions is true: (A) the statement is accompanied by 'meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement'; or (B) plaintiffs fail to establish that the statement was 'made with actual knowledge … that the statement was false or misleading.'" 1/29 Order at 12 (citation omitted); *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. West Holding Corp.*, 320 F.3d 920 (9th Cir. 2003) ("a person may be held liable if the 'forward-looking statement' is made with 'actual knowledge . . . that the statement was false or misleading.'"). The Court found that Defendants' forward-looking statements were not accompanied by cautionary language sufficient to satisfy the first prong of the safe harbor because the cautionary language was "not meaningful and did not identify specific important factors that could affect the prediction." 1/29 Order at 13. However, the Court concluded based on a different set of allegations that Defendants' statements before April 13 were protected by the PSLRA safe harbor's second prong because the statements "may have been made in the optimistic belief that the transgenic testing problem was a surmountable barrier to FDA approval." *Id.* at 14.

Defendants had no basis to believe that Velac would be approved by the PDUFA date or to include Velac-related revenue in their 2005 financial projections. Once Velac tested positive in the Mouse Study, the FDA would not approve it without further additional carcinogenicity testing – which would takes at least six months if not years, with no indication that Velac would ever pass the test. ¶¶97-98. As the Court has already concluded Defendants' statements were not accompanied by meaningful cautionary language, and because the Complaint raises a strong inference of scienter, Defendants' statements concerning the likelihood of FDA approval and the revenue potential for Velac are not protected by the PSLRA safe harbor.

However, Defendants' statements are not forward looking because they failed to disclose the Mouse Study results and the Toxicology Panel's conclusions, which were historical facts.

This Court has previously held that statements similar to Defendants' here are not forward looking "when the defendants possessed and failed to disclose detailed information about the FDA's serious reservations concerning [a drug's] safety and efficacy, they failed to disclose historical facts." *CV Therapeutics*, 2004 U.S. Dist. LEXIS 17419, at *33. The Court further held: "The fact that defendants used those inadequately disclosed historical facts to support unsound projections does not shield their alleged misrepresentations as forward-looking statements." *Id*. Here, as in *CV Therapeutics*, Defendants possessed material, historical facts that they concealed while making misleading positive statements to the public.

Even if a statement is forward-looking, identified as such, and accompanied by meaningful cautionary language, the Ninth Circuit holds that "a person may be held liable if the 'forward-looking statement' is made with 'actual knowledge . . . that the statement was false or misleading.'" *America West*, 320 F.3d at 936. Here, Defendants knew that their statements concerning the approval of Velac by the PDUFA date were certainly misleading in light of the Mouse Study results. As such, these statements are not protected by the PSLRA safe harbor.

"Projections and general statements of optimism" may be actionable "if ***any*** of the following three factors are accurate: (1) the statement is not genuinely believed; (2) there lacks a reasonable foundation for the belief; or (3) the speaker is aware of undisclosed facts that tend to discredit the accuracy of the projection." *In re InterMune, Inc. Sec. Litig.*, 2004 U.S. Dist. LEXIS 15382, at *11-12 (N.D. Cal. July 30, 2004). Here, all three factors are true. As set forth above, Defendants did not genuinely believe, and had no basis to believe, that Velac would be approved prior to the PDUFA date because of the required additional testing. ¶¶94-99. Moreover, Defendants cannot reasonably dispute that they were aware of an undisclosed fact (the Mouse Study) that ***tended*** to discredit the accuracy of their projection (that Velac would be approved by the PDUFA date). In *InterMune*, the Court refused to find that defendants' statements were "protected by the general safe harbor provision" because the Court could not "conclude at this early stage whether defendants relied on the most accurate information or whether they failed to discuss negative information." *Id*. at *15. As set forth above, the Mouse Study was material, negative information that Defendants refused to disclose.

Defendants cite several authorities for the general proposition that a forward-looking statement is not actionable merely because a defendant is aware of some adverse information. Connetics MTD at 18. Defendants assert that in *In re Syntex Corp. Sec. Litig.*, 95 F.3d 922 (9th Cir. 1996), the Ninth Circuit "rejected claims virtually identical" to Lead Plaintiff's allegations. Connetics MTD at 18. *Syntex* actually supports denying Defendants' motion. In *Syntex*, the Ninth Circuit concluded defendants "could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval by the estimated date." *Syntex Corp.*, 95 F.3d at 930. Here, however, this is no basis for Defendants' contention; the required additional carcinogenicity testing would have taken at least six months if not a year and pushed back FDA approval of Velac by at least that much time. ¶¶97-99. "Defendants here cannot legitimately claim they had no knowledge contradictory to their statements." *In re Terayon Communs. Sys. Inc. Sec. Litig.*, 2002 WL 989480, at *3 (N.D. Cal. Mar. 29, 2002) (distinguishing *Syntex*). Defendants' additional authorities cited for the same proposition, *see* Connetics MTD at 18, are distinguishable on the same grounds.

Defendants' rely on *Olkey v. Hyperion 1999 Term Trust*, 98 F.3d 2, 5 (2d Cir. 1996) for the proposition that their statements were protected by the safe harbor regardless of whether they knew their statements to be false. *See* Connetics MTD at 19. As set forth above, however, Defendants' argument fails in two separate respects. ***First***, Defendants' contention is contrary to the law in this circuit. *See, e.g.*, *In re Elec. Arts Inc. Sec. Litig.*, 2006 WL 27201, at *1 (N.D. Cal. Jan. 5, 2006) ("forward-looking statements accompanied by cautionary statements . . . are actionable if knowingly false when made"). ***Second***, this Court has already determined that Connetics' risk disclosures were not adequate. 1/29 Order at 13. Accordingly, *Olkey* is inapposite.

2. Defendants' Statements About Velac's Safety And Efficacy After Learning The Results Of The Mouse Study

In its prior order, the Court found when considering a different set of allegations that Defendants' statements were "made without the disclosure of additional facts that, at the very least, raised serious questions about the drug's safety." 1/29 Order at 15. However, "the Court

[was] unable to hold that plaintiffs have adequately pled that these statements were misleading because this question turns on defendants' knowledge of the transgenic mouse study." *Id*. at 15-16. As set forth above, and in the accompanying Opposition to Motion to Strike, the operative Complaint addresses this issue.

a. Statements In The Company's Form 10-K

In the Company's Form 10-K for 2004 filed on March 16, 2005, Defendants asserted that its testing "demonstrated that Velac was safe and well tolerated." ¶250. Previously, the Court ruled that this statement "may have been misleading because it was made without the disclosure of additional facts that, at the very least, raised serious questions about the drug's safety" and that "a reasonable person certainly would feel misled as to Velac's adverse effects without a disclosure about the disputed, though significant, possibility that Velac was a carcinogen." 1/29 Order at 15. The Court, however, was unable to uphold Lead Plaintiff's claims concerning this statement because the Court struck certain of the allegations. *Id*. at 15-16. The Complaint addresses the Court's prior ruling. ¶¶42-61.

Defendants misstate the Court's holding with regard to the false statement specified in ¶250. Defendants contend: "As this Court has already recognized, the FDA's prior approval of other dermatological products that tested positive in the Tg.AC mouse model provided defendants with ample grounds to believe that Velac was 'safe and effective' as demonstrated by the Phase III clinical trials." Connetics MTD at 22 citing the 1/29 Order at 14. At page 14 of the Court's opinion, upon which Defendants rely, the Court addressed the issue of Defendants' statements concerning FDA approval, and not the separate issue of Defendants' statements concerning Velac's safety.[8] Moreover, the Complaint demonstrates Defendants could not

[8] Similarly, with regard to the statement in ¶250, Defendants rely on the Court's January 29, 2008 Order at 14 to assert the "Court has also recognized that plaintiff cannot allege a 'cogent and compelling' inference of scienter 'because during this time period defendants had not heard anything from the FDA indicating that the FDA had concerns about the results of the transgenic mouse model." Connetics MTD at 23. Again, Defendants are incorrect in applying the Court's analysis of statements concerning FDA approval to this statement about safety.

assume Velac's safety on the basis of the FDA approval of different drugs with different test results. ¶¶122-125.

Defendants' reliance upon *In re Vertex Pharms., Inc., Sec. Litig.*, 357 F. Supp. 2d 343, 352 (D. Mass. 2005) is misplaced. *See* Connetics MTD at 22-23. Defendants erroneously assert that *Vertex* supports their contention that because the FDA approved "other dermal products that tested positive in the Tg.AC mouse model . . . defendants reasonably concluded that Velac was likewise 'safe and effective'" despite the alarming fact that 89 out of 160 of the mice in the study (56%) developed skin tumors. *See* Connetics MTD at 23. Not only is Defendants' argument illogical (it would render the FDA-required preclinical testing meaningless), *Vertex* is inapposite on the facts here. In *Vertex*, the court found that plaintiffs had not adequately pleaded facts attributable to confidential witnesses and therefore failed to plead any facts demonstrating the level of the toxicity of the drug in question and whether the preclinical test results were likely to preclude FDA approval. *Vertex Pharms.*, 357 F. Supp. 2d at 352-354 (finding that "none of the CWs [ ] claim to have personal knowledge of the most important facts they allege."). Here, however, the Complaint pleads ample particularized facts supporting the conclusion that the Mouse Study results would preclude FDA approval prior to the PDUFA date, including: (i) according to the Toxicology Panel picked by the Company, it was unaware of any drug exhibiting a ***similar*** test result that had been approved by FDA (¶94); (ii) according to an expert who served on the Toxicology Panel, the FDA would not approve a drug that tested positive in a Tg.AC study without first requiring additional testing (¶97); and (iii) according to the Company's own former liaison with the FDA, the Mouse Study test result meant that Connetics would have to do a 2 year CARC study to obtain FDA approval (¶98). In *Vertex Pharms.*, plaintiffs merely pleaded the existence of "some" unspecified level of toxicity "without more." 357 F. Supp. 2d at 352. Here, the Complaint unquestionably pleads "more" to demonstrate the results of the Mouse Study were quite significant and made Defendants' statements knowingly false and misleading.

Defendants also assert that they "[were] not required to disclose [ ] concerns or revise their opinion about" Velac as a result of the Mouse Study results. Connetics' MTD at 23 (citing,

among others, *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995)). Defendants' contention is against the great weight of authority holding to the contrary. For instance, in *Amylin*, 2003 WL 21500525, at *8 n.3, the court rejected the holding of *MedImmune*: "The court is not bound by *MedImmune* and disagrees with this holding. If a defendant states that it believes or expects that the FDA will approve its drug but has information tending to seriously undermine the accuracy of its statement, the statement is actionable." *Id.* (citing *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989)); *see also In re Sepracor, Inc., Sec. Litig.*, 308 F. Supp. 2d 20, 34 n.9 (D. Mass. 2004) (same). This Court has likewise declined to follow *MedImmune* and rejected defendants' recitation of the law.[9]

b. Statements In The Company's January 25, 2005 Conference Call

In the Company's January 25, 2005 conference call, Defendant Vontz said: "[W]e know a lot about our product and . . . we're very confident in the data set that we've got. We believe it's ***one of the strongest data sets for an acne product submitted to the FDA***. And we're obviously very excited to launch it. . . . I have a lot of confidence in the strength of our data." ¶243. In the Court's earlier opinion, recognizing that this statement "doesn't fit neatly into any of the three categories," the Court stated that, but for striking certain allegations, it was "inclined to hold that plaintiffs have put forth sufficient allegations to show there was no reasonable basis for the belief that Velac was one of the strongest data sets for an acne product submitted to the

[9] *See CV Therapeutics*, 2004 WL 1753251, at *8-9. Defendants also cite *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212 (S.D. Cal. 2001), which relies upon *MedImmune* and is equally flawed. In *DeMarco*, the FDA did not raise any concerns about the drug until a meeting that occurred on "***the last day of the Class Period***" and therefore defendants could not have made any misrepresentations about the FDA's concerns. 149 F. Supp. 2d at 1216, 1224-25. Defendants' reliance on *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, 2005 WL 4161977 (D. Colo. Oct. 20, 2005) is flawed because plaintiffs there did not specify the materiality of any purported "concerns" raised by the FDA. Moreover, in both *Noble* and *DeMarco*, the FDA eventually approved the drugs in question. Here, Velac was never approved. *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d. 153, 157 (2d Cir. 1998), cited by defendants (Connetics MTD at 24) is also inapposite. Unlike *Carter*, here, defendants had statistically significant scientific evidence that Velac caused cancer.

FDA and that Vontz had actual knowledge of undisclosed facts tending to seriously undermine the accuracy of the statement." 1/29 Order at 16.

With respect to ¶243, Defendants contend "plaintiff wrongly attributes the statements to Mr. Vontz and then takes the statements out of context by intentionally deleting sections . . . . Mr. Wiggans was merely offering an opinion on the ability of Velac to ***compete*** against other acne products." Connetics MTD at 25-26 (emphasis in original). According to the Complaint and the Final Transcript of the conference call produced by Thomson StreetEvents, the speaker was Vontz. Defendants previously made this same contention that Lead Plaintiff has somehow taken Mr. Vontz's statement out of context (*see* Reply Memorandum in Support of Motion to Dismiss Plaintiffs' Amended Consolidated Class Action Complaint [Dkt. No. 54] at 12). The Court should again reject Defendants' strained reading of Vontz's clear statement that is directly at odds with the results of the Mouse Study then known to him. At minimum, it is a factual question as to how Vontz's statement would have been understood by a reasonable investor, which should not be resolved on motion to dismiss. *See Berson*, 2008 U.S. App. LEXIS 11982, at *8, *11 (rejecting defendants' "conceivable interpretation" of a statement upon concluding the panel could not rule as a matter of law reasonable investors would have understood defendants' statement); *Acme Propane, Inc. v. Tenexco, Inc.*, 844 F.2d 1317, 1324 (7th Cir. 1988) (under Rule 12(b)(6), court must accept plausible interpretation of defendants' statement that is "most favorable to the plaintiffs"); *In re Ashanti Goldfields Sec. Litig*, 184 F. Supp. 2d 247, 268 (E.D.N.Y. 2002) (noting that "all reasonable inferences must be drawn in favor of the plaintiff" court denies motion to dismiss as to "ambiguous" statement).[10]

Defendants further contend that the statement in ¶243 is "supported" – despite the results of the Mouse Study and the conclusions of the Toxicology Panel – by, among other things, "the

[10] The statement at issue is at page 18 of Exhibit 2 to the Steskal Declaration. Defendants cite page 2 of the same Exhibit in support of their contention that the statement merely concerned the "ability of Velac to compete against other acne drugs." Connetics MTD at 26, fn. 28. Defendants should not be permitted to pull in far-flung "context" to rewrite a statement that is, on its face, a clear and unmitigated endorsement of the entire data set provided to the FDA as the best for any acne medication ever provided to the FDA.

large number of products that had been approved despite a positive response in animal carcinogenicity studies" and the "high number of 'false positives' associated with the Tg.AC study." Connetics MTD at 26. These facts, however, are not properly before the Court and are contested by Lead Plaintiff. *See supra* pages 9-11. In particular, the FDA requires that positive-testing drugs undergo additional testing prior to obtaining FDA approval. ¶¶97-98. Connetics had not done this additional testing. Moreover, Defendants *post hoc* citation of a few instances where different drugs were approved says nothing about their state of mind at the time or the percentage of drugs that test positive and the FDA rejects. Indeed, Defendants offer only one example of a drug that was ever approved after its vehicle (like the vehicle in Velac) tested positive, and no indication that they were even aware of the drug at the time. Moreover, Defendants proffer no evidence that the Tg.AC mouse study results in a "high-number" of false positives – much less explain why the FDA would endorse such a test.

Finally, Defendants argue that ¶243 is merely a "generalized assertion[] of corporate optimism . . . too vague and unspecific to be actionable under the federal securities laws." Connetics MTD at 27, fn 29. Defendants are incorrect. As this Court previously held: "Opinions such as these are actionable . . . where the 'speaker is aware of undisclosed facts tending to seriously undermine the accuracy of the statement.'" 1/29 Order at 16 (citation omitted). Here, Vontz's statement concerning Velac ("[W]e know a lot about our product and . . . we're very confident in the data set that we've got. We believe it's ***one of the strongest data sets for an acne products [sic] submitted to the FDA***.") was neither vague nor unspecific, but was an unqualified endorsement of the Company's most important new product without any disclosure of a material fact known to Defendants. Vontz's statement "cannot be evaluated without regard to what [Vontz] omitted to say." *InterMune*, 2004 U.S. Dist. LEXIS 15382, at *18.

3. Defendants Made False And Misleading Statements After April 13 Concealing The FDA's Explicit Concerns

On April 13, 2005, Connetics held a private conference call with members of the FDA's ECAC, during which the FDA told Defendants that Velac "may be a tumor promoter or a

carcinogen" and "this is a serious issue for a topical product for the treatment of acne." ¶¶107-108. According to CW6, the Company's former liaison with the FDA, it was clear that Velac was not likely to be approved. ¶¶43(f), 107-108. As the Court recognized in its Order, this was "significant and material information." 1/29 Order at 17. Recognizing this material information had to be disclosed to the market, on April 14, 2005 the Company instituted a ban on trading in Connetics' securities by anyone who attended the ECAC Conference Call or was involved in preparing regulatory submissions for Velac. ¶110.

a. After The FDA Told Defendants Velac Was Not Likely To Be Approved, Defendants Touted Velac At Connetics' Investor Conference

The day after the ECAC Conference Call, April 14, 2005, Defendants hosted Connetics' Annual Analyst and Investor Day. During the Annual Analyst and Investor Day, and in a subsequently issued press release, Defendants increased the Company's projected revenues for 2005 from between $190 - $200 million to $195 - $206 million. ¶254. This revenue guidance assumed revenues from Velac in 2005, beginning at or around the PDUFA date. ¶112. By increasing guidance, Defendants were clearly signaling to the market that Velac approval was still anticipated by the PDUFA date. ¶259. This was a knowing deception.

During the Annual Analyst and Investor Day, Defendants also made a favorable presentation concerning Velac while failing to disclose that Defendants had already been told by the FDA that Velac was not likely to be approved. The Annual Analyst and Investor Day information was available to investors via webcast and was reported on by a number of analysts. ¶254. For instance, several analysts covering the Company commented on management's "enthusiastic" review of Velac, that the Company was "confident in approval," and that the "Velac clinical data is solid." ¶¶256-258. Specifically, "Connetics provided additional clinical info on Velac. . . . The ***company disclosed*** that both of its pivotal phase III trials achieved statistical significance (95% confidence level) on the primary endpoint of ISGA (Investigator Static Global Assessment) on all three arms of the trial – vs. placebo, clindamycin and isotretinoin as single agent therapy." ¶256. Defendants' positive spin on Velac misled investors.

Defendants contend that Lead Plaintiff "cannot plead a claim based on statements made by third-party analysts" unless a defendant "'adopted, endorsed or sufficiently entangled itself' with such statements." Connetics MTD at 21-22, n.22. Defendants' authorities, however, are "inapt" because they concern cases that "address projections made by third parties, not statements (including forecasts) made by defendants and communicated via third parties." *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1234 (9th Cir. 2004). Here, the statements are traceable directly to Connetics and Defendants. *See, e.g.* ¶256 ("Connetics provided" and "The company disclosed"). This Court previously rejected the same argument Defendants now make, stating "liability can attach when a defendant directly provides false or misleading information to an analyst with the intent that the analyst will communicate the information to the market. . . . A company may not lie to securities analysts and avoid liability for its misrepresentations by refusing to adopt the analyst reports incorporating the misrepresentations." *CV Therapeutics*, 2004 U.S. Dist. LEXIS 17419, at *35; *see also Warshaw*, 74 F.3d at 959 ("if defendants intentionally misled securities analysts and the press in order to stave off a Xoma stock sell off, then . . . [defendants] cannot escape liability"). As this Court held in *CV Therapeutics*, Defendants made misleading statements concerning a drug's "safety and efficacy, despite their knowledge of the FDA's specific and serious reservations" and therefore the motion to dismiss should be denied.[11]

b. Defendants' April 26 Press Release And Conference Call Purposefully Misled Investors

On April 26, 2005, Defendants belatedly (and misleadingly) disclosed that on April 13, 2005 the FDA was "interpreting some of the results" of testing differently than the Company but that the "Company carefully analyzed the results with a panel of leading toxicologists" and that the expert panel concluded that the test results were not problematic. ¶¶116-117. *See also*

[11] 2004 U.S. Dist. LEXIS 17419, at *27-28. Defendants also challenge ¶252 as pertaining to a statement made by an analyst not "adopted" by Defendants. Connetics MTD at 21, fn. 22. The analyst, however, specifically states he met with Defendant Higgins and attributes the quoted text to Connetics. *See* ¶252. These are statements made by Defendant Higgins and Connetics, not by the analyst, and are therefore actionable.

¶¶260-261. In addition, on April 26, Defendants misleadingly assured investors that the Company still anticipated earning $20 million in Velac revenue in 2005 – which would not be possible unless the Company obtained FDA approval of Velac by the PDUFA date. ¶118. *See also* ¶¶263-265. Indeed, Higgins expressly stated on April 26 during the conference call: "We are, of course, forecasting the launch of Velac in the third quarter at this time with this guidance." ¶264. Higgins' assurance that Connetics would recognize Velac revenue in 2005, despite the ECAC conclusions, was contrary to the true facts known to Higgins. ¶265.

The Court previously held that, but for striking certain allegations as previously pleaded, Lead Plaintiff had adequately alleged that the Company's April 26, 2005 statements were false and misleading because "defendants had an obligation to disclose to investors the significant and material information regarding the FDA's statement that the possible carcinogenic effect of Velac was a 'serious issue.'" 1/29 Order at 17. The Complaint now demonstrates that its allegations are properly pleaded. *See* ¶¶42-61.

Defendants assert that the market was not misled by the April 26 statements, and, therefore, Defendants could not have believed they were misleading investors because: "After the disclosures, Connetics stock dropped, and analysts predicted a delay in approval, indicating that the market understood the potential seriousness of the issues." Connetics MTD at 29. This argument fails in several respects. ***First***, Defendants' contention is contrary to the Court's prior order finding the market was misled because Defendants failed to disclose the seriousness of the FDA's concerns. 1/29 Order at 17. ***Second***, the fact that Connetics stock dropped does not prove the market was told the full truth. Had the full truth been told, as the law requires, the market would have reacted more negatively and the stock would have dropped more. Indeed, analysts were deceived by Defendants' April 26 statements. *See, e.g.* ¶127 ("***management believes it can address FDA commentary with existing data***" (emphasis in original)).[12] ***Third***, the market was clearly misled as to the severity of the issue. For instance, Defendants told

[12] Indeed, at least one analyst believed approval was likely because Velac's two active ingredients had already been approved by the FDA. ¶125. What this analyst, and others, did not know was that the Velac vehicle – not the active ingredients – caused the tumors in the Mouse Study. ¶¶93, 125.

investors that only one mouse had developed tumors when, in fact, 89 of 160 mice were affected. ¶266. ***Fourth***, Defendants' argument is inappropriate for resolution by the Court. "[W]hether adverse facts were adequately disclosed is a mixed question to be decided by the trier of fact." *Fecht v. Price Co.*, 70 F.3d 1078, 1081 (9th Cir. 1995). *See also Warshaw*, 74 F.3d at 959 (where defendants knew of FDA's concerns about a drug, and disclosed "risks of failure involved in the FDA process," court cannot say that as a matter of law that statements were not misleading).

Defendants further contend that it is "inherently illogical" to suggest that Defendants "voluntarily decided to share information with the market, yet deliberately decided to tell half-truths" and therefore this negates any inference of scienter. Connetics MTD at 28. Not so. Whatever Defendants' motives, which Lead Plaintiff need not plead,[13] the fact remains that Defendants told half-truths in their April 26 statements. For instance, Defendant Yaroshinsky, who attended the April 13 ECAC Conference Call and learned Velac was not likely to obtain FDA approval by the PDUFA date, recognized that Defendants' statements to the market were misleading and he made substantial (and illegal) trades betting that Connetics' stock would plummet further.[14]

Defendants finally contend that they acted "reasonably" in making the April 26, 2005 statements disclosing some, but not all, of the pertinent information concerning the ECAC Conference Call because, according to Defendants' assertions outside the pleadings, "ECAC is only one of several advisory committees and that its views are not binding on the FDA" and that "defendants knew that the FDA could still reject ECAC's views." Connetics MTD at 29-30.

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[13] *Tellabs*, 127 S. Ct. at 2511 ("absence of a motive allegation is not fatal"). *See also In re Apollo Group Inc. Sec. Litig.*, 395 F. Supp. 2d 906, (D. Ariz. October 18, 2005) ("it does not appear to the Court that motive is a required element," *citing Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001)).

[14] ¶¶133-42. Lead Plaintiff disputes Defendants' contention that they were under no obligation to reveal the contents of the ECAC Conference Call. Regardless of the existence of an independent duty to disclose, Defendants did make statements concerning the ECAC Conference Call and were therefore obligated to tell the whole truth. *See, e.g. Berson*, 2008 U.S. App. LEXIS 11982, at *11 ("once defendants chose to tout the company's backlog, they were bound to do so in a manner that wouldn't mislead investors as to what that backlog consisted of").

This argument is flawed in numerous respects. Defendants posit no factual support whatsoever, and cannot on this motion to dismiss, suggesting the FDA regularly rejects the conclusions of its own carcinogenicity committee, ECAC, and approves potentially carcinogenic drugs without further time-consuming tests. Defendants do not, and cannot, dispute that the ECAC is the primary resource for the FDA on carcinogenicity issues. ¶107. The notion that defendants' supposedly boundless optimism in obtaining FDA approval by the PDUFA dates eliminates the ECAC's serious, express concerns fails to warrant dismissal as a matter of law.

Here, as in *CV Therapeutics*, the "Complaint specifically alleges that the defendants fraudulently and misleadingly failed to reveal the depth of the FDA's concerns." 2004 U.S. Dist. LEXIS 17419, at *26. This is sufficient to defeat a motion to dismiss.

c. Defendants Misleadingly Compared Velac To Benzoyl Peroxide And Falsely Stated "Only One Mouse" Developed Tumors In The Mouse Study

During the Company's April 26 conference call, Defendants told investors that benzoyl peroxide/BenzaClin had tested positive in a Tg.AC test but had been approved by the FDA. ¶120. *See also* ¶263. In addition, management falsely told the analyst at Jeffries & Company, Inc., David H. Windley, that "only one mouse" developed skin tumors in the Tg.AC mouse testing of Velac. ¶266. These statements were knowingly false and misleading. As Defendants knew, Velac caused tumors in 89 of 160 mice in the study – not just one mouse. ¶92. Comparing the novel vehicle in Velac to benzoyl peroxide/BenzaClin was misleading for a number of reasons. ¶¶121-125. In particular, Defendants offer no basis to believe that benzoyl peroxide/BenzaClin resulted in a positive Tg.AC mouse test of the same significance as did Velac, which level of tumor promotion (56%) was so extremely high that the Panel told Connetics that no other drug with this high a positive dermal had ever been approved by the FDA.[15] The product inserts for BenzaClin fail to disclose a number of critical facts necessary to draw any comparison between Velac and benzoyl peroxide/BenazaClin, including what

[15] ¶¶94, 121. The record before the Court does not show whether benzoyl peroxide caused tumors in 1% or 56% of mice. Thus, asserting Velac is "similar" to benzoyl peroxide/BenzaClin is meaningless.

additional testing was required before BenzaClin could be approved by the FDA. ¶122. Moreover, there are significant reasons to not compare Velac to BenzaClin (¶123) and to not do so on the basis of a product insert (¶124).

d. Allegations Concerning The FDA's Conclusions Regarding Velac Are Well Supported

Defendants assert "plaintiff does not allege any facts establishing that any defendant was present for the ECAC call or made aware of the putative statement[s]" made by the FDA concerning Velac. Connetics MTD at 27. Defendants' argument ignores the Complaint's allegations. On April 14, 2005 – the day after the ECAC Conference Call – the Company instituted ban on trading in Connetics' securities by anyone who attended the ECAC Conference Call or was involved in preparing regulatory submissions for Velac. ¶110. This trading ban could not have been instituted without Connetics' senior officers – the Insider Defendants – being made aware of what occurred during the ECAC Conference Call. *Id.* Whether the Defendants attended the ECAC Conference Call or learned what happened shortly thereafter is irrelevant – Defendants were clearly made aware of the FDA's conclusion that the Mouse Study results were a "serious" impediment to approval of Velac. ¶¶107-110. Scienter, therefore, could hardly be stronger. *See Berson*, 2008 U.S. App. LEXIS 11982, at *17 (it is "'absurd to suggest' that top management was unaware" of prominent issues faced by the company that are pleaded with particularity). *See also In re Dura Pharm., Inc. Sec. Litig.*, 2008 U.S. Dist. LEXIS 12923, at *36 (S.D. Cal. Feb. 20, 2008) (strong inference of scienter found based upon "length of time" of problem, the "gravity of the problems," defendants' attendance at "development meetings" and "the NDA's failure for the very reasons identified . . . during the product development meetings").

Defendants attempt to attack the credibility of CW6. Connetics MTD at 27-28. According to Defendants, CW6 "negates any inference that defendants intended to mislead investors" in the April 26 statements concerning the ECAC Conference Call. *Id*. at 3. CW6 attended the ECAC Conference Call, and personally witnessed the ECAC tell Connetics that approval of Velac was not likely. ¶¶43(f), 108. The Complaint satisfies the Ninth Circuit's requirement that a source, CW6, be "described 'with sufficient particularity to support the

probability that a person in the position occupied by the source would possess the information alleged' and the complaint contains 'adequate corroborating details.'" *In re Daou Sys. Inc., Sec. Litig.*, 411 F.3d 1006, 1015 (9th Cir. 2005). Lead Plaintiff does not rely solely upon CW6's account of the ECAC Conference Call. Lead Plaintiff also relies upon Defendants' admissions and the record from the SEC proceedings. ¶¶48-55, 108; *see also* Opp. to MTS. Moreover, the SEC's and CW6's account of the ECAC Conference Call are corroborated by, among other things, (i) Yaroshinsky's massive insider sales after the ECAC told the Company of its concerns, (ii) the Company's trading ban, (iii) the account of CW4 that Velac caused a high incidence of tumors and that Defendants met to discuss how to "risk mitigate" this news (¶91), and (iv) the account of CW5, that a 20% tumor rate was clearly significant (¶96), which would support the conclusion that the ECAC would find a 56% tumor rate alarming.

4. Taken Collectively, The Allegations Raise A Strong Inference Of Scienter

Scienter allegations must be "taken collectively." *Tellabs*, 127 S. Ct. at 2509. While Lead Plaintiff does not rely on motive allegations to plead a strong inference of scienter, Defendants' insider selling (¶¶328-331), desire to raise financing (only a few weeks before disclosing the truth about Velac) (¶¶317-320), and bonus-payments all support an already strong inference that Defendants purposefully concealed the truth about Velac (¶¶333-342). Defendants argue that because Krochmal did not sell stock, this negates a strong inference of scienter. Connetics MTD at 31. Not true. *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 944 (9th Cir. 2003) ("Scienter can be established even if the officers who made the misleading statements did not sell stock during the class period."). Moreover, as set forth in the Complaint, Krochmal did not join the Company until shortly before the Class Period and did not have many shares to sell. ¶331. Defendants attack the remaining motive allegations as independently insufficient to support a strong inference of scienter, but taken together these facts are consistent with, and supportive of, Lead Plaintiff's allegations that Defendants acted with intent to deceive.

C. Defendants Purposefully Falsified Connetics Financial Statements And Misled Investors Concerning Connetics' Inventory Problems

1. Connetics' Financial Statements Were Admittedly False When Issued

"[D]efendants admit that their financial statements were misstated with regard to reserves." 1/29 Order at 19. The Company's restatement was due to admitted errors in its previously published financial results, errors which existed at the time the financial statements were released and were not the result of new information, subsequent developments or a change in accounting rules. ¶¶186-190. "Therefore, only scienter . . . is at issue with regard to the false financial statements." *Id.* As set forth below, the Complaint alleges a strong inference of scienter.

2. Defendants Misled The Market Concerning Connetics' Shipping Policies And Distributors' Inventory Levels

In addition to falsifying the Company's financial statements, throughout the Class Period, Defendants repeatedly – and falsely – reassured investors the Company was not shipping excess product to distributors. For example, throughout the Class Period, in each of the Company's Form 10-Ks filed with the SEC, Defendants reassured investors the Company did not ship excessive product but, rather, maintained inventory levels at distributors that were consistent with product demand: "***We try to maintain inventory levels that are no greater than necessary to meet our current projections.***" ¶162. Investors were keenly concerned that shipments to distributors did not exceed end-user demand, as illustrated by this exchange between Defendant Higgins and an analyst in August 2005:

> **Analyst:** . . . And what were inventory levels for all products at the end of the quarter? How does that compare to last quarter? And then, specifically, on Soriatane and Evoclin, obviously those numbers came in pretty strong. Was there any stocking there, or does that truly reflect that prescription demand for those products?
>
> **Higgins:** . . . ***we're spending more time matching shipments to demand***, that's one of our objectives, I think with regard to your previous question, the levels of inventory at the end of this quarter, versus last quarter [are] fundamentally unchanged.

¶276. Similarly, on the December 19, 2005 Conference Call, Defendant Wiggans had the following exchange with an analyst:

> **Analyst:** Okay. And, then, maybe just following up on that, could you just kind of give us a sense, then, sort of where you expect to be at year end in terms of wholesaler inventory levels on the range of products in the portfolio?
>
> **Wiggans** Well, we've always – I mean, ***we track, now, shipments to demand. We have for some period of time.*** And so we, again, ***we don't see any fundamental changes in our inventory levels.***

¶287. *See also* ¶¶304-306. These statements were false and misleading because Defendants were personally directing Connetics employees to ship product to distributors in excess of end-user demand in order to artificially inflate the Company's earnings. ¶¶163-176.

In addition to falsely stating that the Company did not ship product in excess of end-user demand, Defendants assured investors throughout the Class Period that the Company closely monitored distributors' inventory levels in numerous ways so that Connetics accurately understood the amount of product held by distributors. For instance, the Company's Form 10-K filed with the SEC on March 15, 2004 reassured investors the Company could estimate wholesaler/distributor inventory levels without relying upon those distributors:

> We monitor wholesaler inventory ***using a combination of techniques***, including evaluating how much inventory is sold through to the wholesalers' customers, which we do ***by tracking the prescriptions filled for our products at the pharmacy level***. . . . We estimate prescription demand for our products primarily by analyzing third-party syndicated data sources that ***track prescriptions written by health care providers and dispensed by licensed pharmacies***.

¶158. Similarly, during a Conference Call with investors and analysts on August 2, 2005, Defendant Wiggans stated that changes to the Company's distribution service agreements in 2004 allowed the Company to have "considerably more information about the inventory levels and channel distribution by the wholesalers" and the Company was "monitoring the shelf life of existing product as it moves through the distribution channel going forward." ¶¶161, 275-276. These statements were misleading because, while monitoring, Defendants shipped excess inventory that could be returned when the product approached expiration (and this would be very expensive to the Company). Because the Company shipped excess product to distributors, thereby inflating the distributors' inventory levels such that shipments would have to be curtailed for nearly all of 2006 (¶¶176, 182), Defendants' statements that they closely monitored

inventories were misleading. *See, e.g., Berson*, 2008 U.S. App. LEXIS 11982, at *6 (a "statement is misleading if it would give a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists'"); *Miller v. Thane Int'l, Inc.*, 2007 U.S. App. LEXIS 27316, at *14 (9th Cir. Nov. 26, 2007) ("[S]tatements literally true on their face may nonetheless be misleading when considered in context."). *See also* 9th Cir. Civ. Jury Instr. 18.0 (2007).

3. Defendants Purposefully Manipulated The Company's Reported Financial Results And Misled Investors Concerning Inventory Issues

A § 10(b) complaint must allege facts giving rise to a strong inference that the defendants acted with the required state of mind. 15 U.S.C. § 78u-4(b)(2). The required state of mind is satisfied where, as here, the complaint alleges defendants acted either knowingly or with deliberate recklessness. *See Oracle Corp.*, 380 F.3d at 1230. In *Tellabs,* the Supreme Court defined the "strong inference" standard as follows: "When the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" 127 S. Ct. at 2511, 2513. "[T]he court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically." *Id.* at 2511. Here, when viewed collectively, there is ample factual support for a strong inference of scienter.

The Complaint, as a whole, alleges that senior management purposefully falsified the Company's financial results and misled investors. Defendants personally instructed employees to ship more product to distributors than the end-users were demanding, despite the fact that these employees specifically told Defendants that the shipments were causing excess inventory buildup at the distributors. ¶¶166, 171-173. According to the Company's former employees, who were in a position to know, Defendants increased sales at the end of each quarter specifically to meet financial projections. ¶171. Defendants also instructed these former employees to falsify internal demand projections to purportedly justify these shipments. ¶170. Defendants employed a return policy that encouraged the Company's distributors to take excess product. ¶¶154, 168. Defendants told investors that they closely monitored distributors' inventory levels and the number of prescriptions being written for Connetics drugs (¶¶157-158),

told investors that the Company only shipped enough product to meet demand from actual patients filling prescriptions (¶¶157-162), and told investors that inventory levels had not increased (¶¶276, 287, 302, 305). Yet, the Company now admits it over-shipped product to distributors in excess of product demand and it would have to reduce shipments for over a half year to reduce distributors' excess inventory levels. ¶182. The Company has further admitted that it failed to properly reserve for returns of expired (or nearly expired) inventory from distributors. ¶187. And, Defendants have admitted that reserving for such returns was one of the Company's "critical accounting policies" that they "reviewed." ¶157. These facts more than sufficiently demonstrate that Defendants' were not in the dark about inventory levels at the Company's distributors.

a. The Accounting Violations Were Too Obvious To Be Mistakes

Defendants' GAAP violations are of such a nature as to strongly support a strong inference of scienter. *See Daou*, 411 F.3d at 1022 (significant GAAP violations can provide evidence of scienter so long as they are pled with particularity). "[U]pon the laying of a proper factual foundation that information was known within a corporation, it may be inferred that facts critical to a business's core operations or an important transaction are known to a company's responsible officers." *In re LDK Solar Sec. Litig.*, 2008 U.S. Dist. LEXIS 42425, at *44 (N.D. Cal. May 29, 2008). *See also Berson*, 2008 U.S. App. LEXIS 11982, at *13 (finding a strong inference of scienter where defendants "were directly responsible for [Company's] day-to-day operations.")

For instance, the Company's Restatement admits that Defendants calculated reserves without taking into account the fact that distributors who returned expired product oftentimes received far in excess of the initial sale price that the distributor paid:

> ***[W]e calculated the value of the estimated units to be returned using the original sales price without taking into account price increases that were implemented between the date of sale through the period of the accrual.*** We permit wholesalers to return expired or expiring product for a credit at the then-current sales price less 5%, so the initial sales price may not fully capture our liability for future returns. As a result of our evaluation, we determined that our accrual for product returns had been understated and concluded that the impact of the errors required us to restate our financial statements for prior years.

¶188. The Company's SEC filings assured investors that the Company's senior management reviewed the Company's accounting for its reserves, as this was one of the Company's "critical accounting policies." ¶157. Defendants would have this Court infer that Defendants simply were not aware of the Company's returns policy when they established the Company's reserves. No such inference is warranted. The Company had only three major distributors (¶149), and the level of inventories and potential for returns was of critical importance to the Company and Defendants. ¶157.

b. After Defendants' Repeated Assurances That They Monitored Inventory Levels, They Cannot Now Claim Ignorance

"The most direct way to show both that a statement was false when made and that the party making the statement knew that it was false is via contemporaneous reports or data, available to the party, which contradict the statement." *Oracle Corp.*, 380 F.3d at 1230. Here, Defendants repeatedly assured the market they were closely monitoring distributors' inventory levels and utilizing a "combination of techniques" to do so. *See, e.g.* ¶158. Connetics contractually required its distributors to provide information about inventory levels and channel distribution. ¶161. Separate and independent of any information provided by distributors, Connetics monitored distributors' inventories by knowing exactly how much product the Company shipped to the distributors and by using a sophisticated monitoring system to know how much product was being used by actual patients. ¶160. Defendants determined actual demand for the Company's drugs "by analyzing third-party syndicated data sources that track prescriptions written by health care providers and dispensed by licensed pharmacies" and by purchasing data on prescriptions filled from Per-Se Technologies, formerly NDC Health Corporation, one of the leading providers of prescription-based information. ¶¶158, 159. Where, as here, defendants tout their ability to monitor and see potential problems, they cannot then now claim to be in the dark. *See, e.g.*, *Daou*, 411 F.3d at 1022 ("specific admissions from top executives … that they monitored portions of the company's database are factors in favor of inferring scienter"); *Oracle Corp.*, 380 F.3d at 1234-35 (same); *Atlas v. Accredited Home Lenders Holding Co.*, 2008 U.S. Dist. LEXIS 3863, at *31 (S.D. Cal. Jan. 4, 2008) (scienter

found where defendants "implemented a system specifically to monitor" the issues in question); *In re PeopleSoft, Inc., Sec. Litig.*, 2000 U.S. Dist. LEXIS 10953, at *8 (N.D. Cal. May 25, 2000) ("Senior management affirmatively touted its long-term 'high visibility' to see into the future and to make reliable forecasts . . . . This same visibility can be presumed to have given them the ability to see the downturn before it was reported.").

Attempting to create a factual dispute, Defendants contend that: "Connetics' reserve estimates were impacted by inaccurate and inconsistent inventory level reports provided by its three main wholesale customers." Connetics MTD at 13, fn. 14. The contention that all three of Connetics' main distributors simultaneously, but independently, provided Connetics with faulty information is incredible – particularly in light of the accounts of confidential witnesses and the fact that Connetics was able to independently determine inventory information based upon prescription data provided by independent third parties. Moreover, as set forth in the Complaint, the Company's restatement provides an Explanatory Note for the Company's restatement that expressly rules out Defendants' contention. *Id*. As the Explanatory Note details, the necessity for restating the financial results was the result of facts known to the Company at the time the prior financial statements were prepared. ¶192. In other words, the Company admitted that it had enough information ***at the time it filed its financial statements*** to prepare them in accordance with GAAP. ¶190.

c. The Complaint Need Not Identify Specific Fraudulent Transactions To Plead Scienter

Defendants admit that Connetics' financial statements were in violation of GAAP because, among other things, Defendants calculated reserves in contradiction of the Company's clear return policy for expired product held by distributors. ¶188. Similarly, the restatement admits that the Company calculated reserves without accounting for "all units with potential risk of return." ¶189. As Defendants admitted in the restatement, the financial statements were false because the Company employed a faulty "methodology for estimating future product returns." ¶187. This faulty methodology was not linked to specific shipments of product, nor was this faulty methodology the result of any one particular fraudulent transaction. Rather, this faulty

methodology applied to the Company's calculation of reserves. Accordingly, Defendants are incorrect to assert that Lead Plaintiff's allegations are not particularized without allegations concerning "specific shipments." Connetics MTD at 34.

The Ninth Circuit has made clear that the pertinent question is not whether a complaint pleads each specific fraudulent transaction but "[whether] plaintiffs have provided enough information for a court to discern whether the alleged GAAP violations were minor or technical in nature, or whether they constituted widespread and significant inflation of revenue." *Daou*, 411 F.3d at 1020. The Ninth Circuit overturned the district court's dismissal (which had found plaintiffs' allegations insufficiently particularized), on the basis of anecdotal accounts of confidential witnesses detailing widespread wrongdoing. *Id*. The Court concluded that "prematurely recognizing millions of dollars in revenue is not minor or technical in nature" and that the complaint stated a claim because it "indicates that these practices allegedly occurred systematically throughout the class period." *Id*.

There is no requirement that a complaint plead specific fraudulent transactions to allege accounting fraud. The First Circuit analyzed this issue in *In re Cabletron Sys*., 311 F.3d 11 (1st Cir. 2002). Like the Defendants here, in *Cabletron* defendants argued "the complaint still leaves too many other unanswered questions -- such as the precise dates of transactions, the names used for phony customers, the identities of corporate personnel involved, the specific products warehoused, or the exact dollar amounts of individual fraudulently recorded sales." *Id*. at 32. The First Circuit rejected this contention, holding: "Each securities fraud complaint must be analyzed on its own facts; there is no one-size-fits-all template. Sufficient evidence of one type might reduce or eliminate the need for evidence in other categories, without thwarting the legislative intent behind the PSLRA." *Id.* Further, the First Circuit cited numerous authorities upholding a securities action in which the plaintiff had not pleaded the types of specific facts that Defendants contend must be pleaded. *Id.* To state a claim for fraud, Lead Plaintiff need not plead every detail of every fraudulent transaction.

Nor do defrauded investors have to plead specific fraudulent transactions to show Defendants knew their statements concerning inventory levels were false and misleading.

Distributors' excessive inventory levels were the result of many quarters of over shipping product – not the result of any specific shipment of product. Accordingly, details concerning a specific transaction are irrelevant here because Lead Plaintiff pleads, as set forth above, that senior employees of the Company personally told Defendants that the Company was shipping too much product to distributors and that inventory levels were too high for demand. ¶¶166-174. And, Defendants had sophisticated mechanisms for monitoring these inventory levels, and reassured investors they were doing so. ¶¶157-162. Here, the inventory levels were so far in excess of user demand that the Company admittedly had to reduce shipments to distributors for most of 2006. ¶182. Such a large problem did not develop over night, raising a strong inference that Defendants knew about it. *See, e.g., In re Number Nine Visual Tech. Corp. Sec. Litig.*, 51 F. Supp. 2d 1, 16 (D. Mass. 1999) (holding that one way to draw a strong inference of defendants' knowledge "would be to examine the nature of the alleged problem and determine how long such a problem typically takes to develop and, hence, how early one could reasonably expect a company to know about the problem and incur disclosure obligations").

Defendants contend that the Complaint fails to plead "channel stuffing" with sufficient particularity because the Complaint "does not offer the name of a single customer, the date or time of any shipment, or the dollar amounts of any transaction." Connetics MTD at 34. In truth, however, the Complaint alleges (i) the names of the distributors who were sent excessive product for the purposes of artificially inflating Connetics' earnings (Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Corporation (¶149)); (ii) the improper shipments occurred in the last two weeks of fiscal quarters during the Class Period (¶171); and, (iii) the amount of excess product shipped was significant, as evidenced by Defendants' admission at the end of the Class Period that inventory levels had grown so large that the Company would have to curtail production shipments for nearly all of 2006 (¶182).

There is, moreover, no need to plead such facts here to state a claim for false financial statements. Numerous employees personally witnessed Defendants directing the Company to ship product that was far in excess of demand, and then falsify the Company's internal

projections purportedly to justify the shipments.[16] *Makor Issues & Rights, Ltd. v. Tellabs Inc*., 513 F.3d 702 (7th Cir. Ill. 2008) is instructive. In *Tellabs*, plaintiffs alleged "Tellabs had been flooding its customers with tens of millions of dollars worth of [product] that the customers had not requested, in order to create an illusion of demand." *Id*. at 706. Writing for the Court, Judge Posner explained that channel stuffing is actionable fraud when used to disguise true demand, and the seller books revenue even though the distributor can return the product: "Channel stuffing becomes a form of fraud only when it is used, as the complaint alleges, to book revenues on the basis of goods shipped but not really sold ***because the buyer can return them***. . . . The huge number of returns [of product] is evidence that ***the purpose of the stuffing was to conceal the disappointing demand for the product*** rather than to prod distributors to work harder to attract new customers, and ***the purpose would have been formed or ratified at the highest level of management***." *Id*. at 709-710. Here, based on the accounts of numerous former employees in a position to know, the Complaint alleges Connetics regularly shipped excess product to distributors to conceal disappointing demand, and that Connetics recognized revenue on these excess shipments even though the distributors had a right of return. ¶¶163-176. Notably, in *Tellabs*, Judge Posner did not mention any requirement that the plaintiffs plead the names of specific customers, dates of specific shipments, or the amounts of specific transactions to plead a claim. Rather, the *Tellabs* court relied on the descriptions of confidential witnesses who were "numerous and consist of persons who from the description of their jobs were in a position to know at first hand the facts" attributed to them. *Makor*, 513 F.3d at 712.

[16] ¶¶166-174. Defendants assert the confidential witnesses are not to be credited because they did not work in "Connetics' finance or accounting department" and other similar assertions. Connetics MTD at 37, fn. 31. Facts attributed to each witness were personally known to them. A national Account Director in charge of sales (CW3) and other sales staff (CW7-CW11) would know whether the Company was shipping excess product solely to meet Wall Street's expectations, as would a former forecaster (CW4). There is no requirement that a witness work in accounting to state a claim for revenue manipulation. *See Berson*, 2008 U.S. App. LEXIS 11982, at *4-5.

d. Defendants Do Not Refute The Strong Inference Of Scienter

Defendants erroneously assert that to establish a strong inference the Complaint must demonstrate that "defendants coerced its customers to accept more product than they wanted." Connetics MTD at 34-35. There is, however, no requirement of "coercion." *See, e.g.*, *Makor*, 513 F.3d 702.

Moreover, Defendants' "coercion" argument ignores Lead Plaintiff's allegations. The Company employed a return policy that rewarded distributors who agreed to accept excess product. Connetics guaranteed distributors the right to return expired or expiring product for a credit at the ***then-current*** sales price less 5%. ¶¶24, 188. Refunds were ***not*** calculated based on what a distributor initially paid for a drug; rather, a refund was based on the price at the time of the return. *Id*. This return policy enabled Connetics' distributors to profit from taking excess inventory because, according to a former National Account Director in charge of Sales Operations, the Company regularly increased prices on drugs by as much as 15-18% twice a year. ¶168. Indeed, Defendants admitted during the Class Period that they knew in 2004 some distributors were engaging in the "forward[] buying of product in anticipation of price increases" – but Defendants falsely assured investors that the Company had "taken the appropriate reserves" to account for these transactions. ¶275.[17]

Defendants also argue there can be no strong inference of scienter as to the manipulation of reserves because Lead Plaintiff does not adequately allege "how any defendant was involved in or knew that the reserves were insufficient, or that any defendant had knowledge of accounting or the level of the reserves." Connetics MTD at 34. To the contrary, these reserves were considered part of the Company's "critical accounting policies" and the Company assured investors that Connetics' "senior management has reviewed these critical accounting policies and

[17] Defendants assert that Lead Plaintiff merely makes unparticularized allegations detailing the "coercive" effect of Connetics' return policy that reward distributors for accepting excessive product. Connetics MTD at 35, fn. 37. This is simply not true given Defendants' statements admitting that they knew distributors engaged in "investment purchasing" and therefore were buying excess product to take advantage of anticipated price increases. ¶275.

related disclosures. . . ." ¶157. Furthermore, Wiggans and Higgins personally signed the Company's SEC filings and certified the accuracy of Connetics' Form 10-Ks and 10-Qs and the accuracy and effectiveness of Connetics' financial disclosures and internal controls over financial reporting. ¶¶34, 36. *See also* ¶¶215, 216, 234, 246, 268, 282, 293. "It would be wholly inappropriate to permit a signatory to evade liability because he/she did not prepare the financial report, as Defendants argue, on the ground that the signatory was unaware of the misstatements made therein. To hold otherwise would effectively eviscerate the entire substance of 18 U.S.C. § 1350, the purpose of which is to ensure that regardless of who prepared the statements, the signatories are attesting to their accuracy and reliability." *Middlesex Ret. Sys. v. Quest Software, Inc.*, 2007 U.S. Dist. LEXIS 84695, at *65-67 (C.D. Cal. Oct. 22, 2007). *See also In re Proquest Sec. Litig.*, 2007 WL 3275109, at *12 (E.D. Mich. Nov. 6, 2007) (rejecting argument that SOX certifications cannot raise a strong inference of scienter and explaining that an officer's "signature will be rendered meaningless unless the officer believes that the statements in the document are true"); *In re Lattice Semiconductor Corp. Sec. Litig.*, 2006 WL 538756, at *17-18 (D. Or. Jan. 3, 2006) (same).).

Attempting to spin the facts, Defendants erroneously assert that "in three quarters, Connetics exceeded guidance even after the restatement (Q1 and Q2 of 2004, and Q3 of 2005)" and that this refutes Lead Plaintiff's theory that Defendants manipulated sales and reserves to meet earnings projections, thereby "negat[ing] any inference of scienter." Connetics MTD at 36. However, Connetics would have missed analysts' forecasted earnings in Q1 of 2004 and missed earnings by a substantial $0.12 per share in 3Q05 but for Defendants' fraudulent accounting. ¶¶325-326 (quoting analyst explaining that the Company's use of one-time gains and accounting changes to boost reported earnings are ignored by analysts who focus upon a company's ongoing operations, and explaining that Connetics only made Wall Street's projected numbers via Defendants' manipulation). Defendants also contend that "Connetics did not meet guidance even before the restatement" in 4Q05, thereby meaning they had no motive to cook the books in that quarter. Connetics MTD at 36. This is illogical; had Defendants not cooked the books in 4Q05, the stock price would have dropped even further when the 4Q05 financial results were

disclosed. Finally, Defendants assert that the restatement caused revenues to increase in two quarters – thereby negating any inference of scienter. Connetics MTD at 36. This is also a *non sequitur*. Even assuming Defendants are correct that Connetics did not report false financial results in two quarters of the Class Period, this does not negate the myriad well-pleaded allegations that Defendants did falsify financial results in the other six financial quarters.

4. The Complaint Amply Alleges Loss Causation Due To Defendants' Manipulation Of Connetics' Financial Statements

Loss causation requires that a complaint allege that the "defendant's misrepresentation . . . proximately caused the plaintiff's economic loss." *Dura Pharm., Inc. v. Broudo,* 544 U.S. 336, 346 (2005). *Dura* holds that at the pleading stage a complaint need only provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind. *Id.* at 347. The loss causation requirement is "not meant to impose a great burden upon a plaintiff" and requires only that a plaintiff provide "notice of what the relevant economic loss might be or of what the causal connection might be between the loss and the misrepresentation." *Id. See also In re Daou Sys.*, 411 F.3d 1006, 1026 (9th Cir. 2005) (loss causation pleaded where stock dropped after "disclosures of [company's] true financial health" after defendants engaged in "practice of prematurely recognizing revenue before it was earned").

Here, the Complaint details how, when the truth about the Company was revealed to the market through a series of partial disclosures, the inflation that had been caused by Defendants' misrepresentations and omissions was eliminated from the stock price and investors, including Lead Plaintiff, suffered losses. *See* ¶¶343-344. In deciding Defendants' first motion to dismiss, the Court held that Lead Plaintiff had sufficiently pleaded it suffered a loss as a result of Defendants' conduct:

> [P]laintiffs also argue that they did own stock in Connetics at the time of other disclosures and drops in the stock price, such as the April 27, 2005 drop of 19% on heavy trading volume, *see* Complaint at ¶ 80, the drop in price around May 4, 2006, *see id*. at ¶ 122, the drop in price on May 22, 2006, *see id*. at ¶ 125, and the 34% drop on heavy trading volume on July 10, 2006, *see id*. at ¶ 129, and ***thus did suffer an injury in fact caused by defendants' actions***. *See also id*. at ¶ 333. ***There is no question that the lead plaintiff has suffered actual injuries related to defendants' alleged actions . . . .***

1/29 Order at 7-8.

Despite the Court's ruling, Defendants assert "Plaintiff cannot allege loss causation. . . ." Connetics MTD at 37. Notably, Defendants do not specifically challenge Lead Plaintiff's allegations concerning loss causation in connection with the April 27, 2005, June 13, 2005, or May 23, 2006 stock price drops. *Compare* ¶343 *with* Connetics MTD a 37-38. Accordingly, Defendants do not challenge loss causation in connection with three of the five stock price declines alleged by Lead Plaintiff and already found sufficient by the Court.

Defendants do contest the stock price declines that occurred on May 3, 2006 and July 10, 2006. Connetics MTD at 37-38. These arguments are without merit. Defendants also do not – and cannot – dispute that previously undisclosed information was revealed on May 3, 2006, when Connetics announced that it would be restating its 2005 financial statements. ¶¶177, 298-307, 343. Defendants argue there is no loss causation because on May 4, 2006, the closing price of the stock was up slightly from the closing price on May 3, 2006. Connetics MTD at 37. However, even though the official press release was issued after the close of the market on May 3, 2006, the information leaked into the market during the trading day on May 3, 2006. ¶343. This is apparent from the ***over 700% increase in trading volume*** from May 2, 2006 (242,800) to May 3, 2006 (1,780,300), and the stock declining 10% on May 3, 2006. ¶343.

Despite the fact that following the July 10, 2006 announcement, Connetics' stock price dropped by nearly $4.00, (or 34%), Defendants claim that the Complaint fails to cite any previously undisclosed information in that announcement. Connetics MTD at 38. The Complaint explains, however, how Connetics disclosed on July 10, 2006 that the Defendants' prior statements about distributors' inventory levels (*see, e.g.* ¶¶182-184) were not only wrong, but the falsehood meant the Company's present and future earnings would be much less than previously expected. Defendants revealed in the July 10, 2006 announcement that Connetics was curtailing shipments to distributors because inventory levels were far too high. ¶182 ("The shortfall in second quarter revenue is due, in part, to the Company's decision to reduce wholesaler inventory by shipping product volumes that were below estimated prescription demand . . . . The Company intends to continue to ship below estimated prescription demand

during the remainder of 2006, with a goal of further reducing average wholesaler inventory levels to approximately two months on hand by the end of 2006."). *See also* ¶343.

Defendants' argument that the Complaint cannot plead loss causation based on the July 10, 2006 disclosure because it occurred one day after the end of the Class Period is likewise unsupported, and makes no sense. Connetics MTD at 37-38. A "class period" defines the class of plaintiffs who bring the lawsuit, *i.e.*, investors who purchased shares at inflated prices and then were damaged when the true facts become known and the stock price declined. Once the "truth" became fully revealed on July 10, 2006, no investor purchasing on or after that date would have a viable claim for fraud in this case, and thus such investors are not included as "class members." Rather, because the truth was revealed on July 10, 2006, the class period ends on July 9, 2006, the last trading day *before* the full truth was revealed. Indeed, the court on remand from the Supreme Court's *Dura* decision rejected a similar defense argument, finding that a corrective disclosure may occur even over nine months after the class period ends.[18]

D. The § 20A Defendants Traded On The Basis Of Material, Non-Public Information

Defendants Higgins, Wiggans, Vontz, Yaroshinsky and Zak (the "§ 20A Defendants") each traded in Connetics securities on the basis of non-public, material information concerning either Velac or the Company's fraudulent accounting practices, and are liable under both §§10b and 20A of the Exchange Act. *See* 15 U.S.C. §78t-1(a); *United States v. O'Hagan*, 521 U.S. 642, 651, 117 S. Ct. 2199, 138 L. Ed. 2d 724 (1997).

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[18] *In re Dura Pharm., Inc. Sec. Litig.*, 452 F. Supp. 2d 1005, 1023 (S.D. Cal. 2006); *cf. Zelman v. JDS Uniphase Corp.*, 376 F. Supp. 2d 956, 966 (N.D. Cal. 2005). Defendants' reliance on *Powell v. Idacorp., Inc.*, 2007 WL 1498881, at *14 (D. Idaho May 21, 2007), is misplaced. Connetics MTD at 38. *Powell* is contrary to Ninth Circuit law. *See id.* at *13-14 (distinguishing Ninth Circuit's *Daou* opinion and rejecting that partial disclosures can satisfy loss causation). Moreover, in *Powell* the truth was not revealed "until well after the Class Period had ended." *Id.* at *13. Here, the Class Period ends the day before the disclosure.

1. Lead Plaintiff Satisfies The Contemporaneous Trading Requirement

"Section 20A of the Exchange Act creates a private cause of action for 'contemporaneous' insider trading. . . . The duration of the period in which an insider defendant's trade can be considered 'contemporaneous' with the plaintiff's is 'not fixed,' and the Ninth Circuit in *Milken* expressly declined to elaborate on its 'exact contours.' As a result, courts have interpreted the requirement in varying ways." *In re Countrywide Fin. Corp. Deriv. Litig.*, 2008 U.S. Dist. LEXIS 40754 (C.D. Cal. May 14, 2008) (internal citations omitted). Rather than a strict reading of "contemporaneously" requiring that a Lead Plaintiff purchased shares on the date of the defendants' sales, "the more persuasive rule" and "the better rule with respect to standing seems to be that a class action may be maintained on behalf of all persons who purchased stock on an exchange during the period that defendants were selling that stock on the basis of insider information." *Middlesex Ret. Sys. v. Quest Software Inc.*, 527 F. Supp. 2d 1164, 1196 (C.D. Cal. 2007).

a. Lead Plaintiff May Bring a § 20A Claim On Behalf Of The Entire Class

The Complaint "alleges that members of the putative class traded [Connetics'] stock contemporaneously with the defendants named in the Section 20A cause of action, and has specified the dates of the defendants' trades. Such averments are sufficient to state a cause of action under Section 20A." *In re Openwave Sys. Sec. Litig.*, 528 F. Supp. 2d 236, 255-256 (S.D.N.Y. 2007). Here, Lead Plaintiff traded contemporaneously with Defendant Higgins, which Defendants concede, and therefore Lead Plaintiff has adequate standing to represent the remainder of the plaintiff class in bringing § 20A claims against all of the § 20A Defendants.

Defendants contend that Lead Plaintiff needs to have standing to bring a §20A claim in its individual capacity against every Defendant in order to assert claims on behalf of the individual class members who purchased contemporaneously with the § 20A Defendants. Yaroshinsky MTD at 9-11. Connetics MTD at 39. As this Court previously recognized, Defendants' standing argument is not supported by authorities interpreting Article III. 1/29 Order at 8. (agreeing with courts finding "once a lead plaintiff demonstrates individual standing

on the basis of its own injury in fact, that is the end of the inquiry and the lead plaintiff has standing to assert other related injuries suffered by members of the class"). Nor is contemporaneous trading with each § 20A Defendant required by § 20A. *See Middlesex Ret. Sys.*, 527 F. Supp. 2d at 1196; *Openwave Sys.*, 528 F. Supp. 2d at 255-256; *In re Cendant Corp. Litig.*, 60 F. Supp. 2d 354, 378-379 (D.N.J. 1999) (allegation that one class representative traded on at least one of the days that the defendant traded satisfied contemporaneous requirement). Finally, Defendants' contention would contravene Congressional intent in passing the PSLRA. The PSLRA authorizes the most adequate lead plaintiff to represent the entire class of investors – even as to claims the lead plaintiff does not have standing to personally prosecute. *See In re Nat'l Golf Props. Sec. Litig.*, 2003 U.S. Dist. LEXIS 4321, at *4-5 (C.D. Cal. Mar. 18, 2003) ("[T]he Private Securities Litigation Reform Act (hereinafter "PSLRA") does not require Lead Plaintiffs to have standing to assert all claims, only that they have the greatest financial stake in the action.").

b. Lead Plaintiff Itself Traded Contemporaneously With Defendants Zak And Higgins

Defendants concede that Lead Plaintiff traded contemporaneously with Defendant Higgins. Connetics MTD at 39. Lead Plaintiff also traded contemporaneously with Zak. Zak sold Connetics stock on April 13, 2005. ¶134. Lead Plaintiff purchased Connetics stock on April 18 and 19, 2005. ¶391. Zak's sales on April 13, 2005 were only three trading days prior to Lead Plaintiff's purchases on April 18, 2005 (April 13, 2005 was a Wednesday). Trading separated by only three trading days is well within §§ 10(b) and 20A's contemporaneous-trading requirement.[19]

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[19] *See, e.g., In re Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133, 138 (S.D.N.Y. 1999) (plaintiff's purchases five days after defendants' sales were contemporaneous); *In re Enron Corp. Sec., Deriv. & ERISA Litig.*, 258 F. Supp. 2d 576, 600 (S.D. Tex. 2003) ("this Court finds that two or three days, certainly less than a week, constitute a reasonable period to measure the contemporaneity of a defendant's and a plaintiff's trades under § 20A"); *In re Eng'g Animation Sec. Litig.*, 110 F. Supp. 2d 1183, 1196 (S.D. Iowa 2000) (purchase three days after defendant's sale contemporaneous).

Lead Plaintiff also traded contemporaneously with Zak's sales of 68,000 Connetics shares between April 14, 2005 and June 10, 2005. ¶134. Defendants incorrectly assert that the Court should simply ignore Zak's sales of 68,000 shares between April 14 and June 10 because Lead Plaintiff "must plead the specific dates" and it is insufficient for Lead Plaintiff to assert that Zak traded "during a certain time period." Yaroshinsky MTD at 9. However, where specific dates of trading are not available without discovery – as is the case here – pleading the exact dates is not required.[20] Here, there is a strong likelihood that defendant Zak traded on the same days as Lead Plaintiff, and it is undeniable that Zak traded in close proximity to Lead Plaintiff, which is sufficient for pleading contemporaneousness required by § 10b and § 20A.

2. Yaroshinsky Is Liable For Tipping Zak

In addition to facing liability for his own illegal insider selling, Yaroshinsky is jointly and severally liable for Zak's trading pursuant to 15 U.S.C. § 78t-1(c). The Complaint more than sufficiently sets forth that Yaroshinsky "tipped" Zak concerning the Company's conference call with the FDA, upon which information Zak traded contemporaneously with Lead Plaintiff and the class. ¶¶133-142.

Yaroshinsky asserts that Lead Plaintiff fails to plead sufficient evidence of Zak and Yaroshinsky's "friendship" to establish the personal benefit requirement of § 20A. Yaroshinsky MTD at 20. However, Lead Plaintiff "need not show that the tipper expected or received a specific or tangible benefit in exchange for the tip. Rather, the 'benefit' element of § 10(b) is satisfied when the tipper 'intends to benefit the . . . recipient' ***or*** 'makes a gift of confidential information to a trading relative or friend.'" *SEC v. Warde*, 151 F.3d 42, 48 (2d Cir. 1998). Yaroshinsky benefitted under both prongs. ***First***, Yaroshinsky intended to benefit Zak by calling him immediately after the ECAC Conference Call (after which Zak immediately sold short

[20] *See, e.g. Neubronner v. Milken*, 6 F.3d 666, 671 (9th Cir. 1993), ("But surely we can not expect a private plaintiff in an insider trading case to plead with the specificity Rule 9(b) requires without allowing some limited opportunity for discovery."); *Countrywide Fin. Corp.*, 2008 U.S. Dist. LEXIS 40754, at *82 (upholding § 20A claim even though "Plaintiffs have not pled with specificity the actual days" of trading); *In re Qwest Communs. Int'l Sec. Litig.*, 396 F. Supp. 2d 1178, 1201 (D. Colo. 2004) (same).

Connetics stock). ¶¶133-134. This is sufficient. *See United States SEC v. Blackwell*, 291 F. Supp. 2d 673, 692 (S.D. Ohio 2003) ("A mere allegation that the insider has disclosed material non-public information is sufficient to create a legal inference that the insider intended to provide a gift to the recipient of the information, thereby establishing the personal benefit requirement." quoting *Dirks v. SEC*, 463 U.S. 646, 664 (1983)). ***Second***, the Complaint sufficiently pleads (based on the SEC Complaint) that Zak was Yaroshinsky's friend and former neighbor. ¶133. Lead Plaintiff need not plead additional facts to establish a "friendship."

3. Yaroshinsky And Zak's Scienter

The Complaint raises a strong inference that Yaroshinsky and Zak knowingly traded on material, non-public information. Yaroshinsky participated in the ECAC Conference Call and immediately telephoned Zak to inform him FDA denial was imminent, after which both defendants (contrary to their prior trading history) entered into transactions calculated to profit when this news was reported to the markets. ¶¶133-142.

Yaroshinsky miscasts Lead Plaintiff's scienter allegations as being "based solely on stock sales." Yaroshinsky MTD at 15. Rather, Lead Plaintiff pleads a strong inference of scienter based on well-pleaded facts detailing, among other things: (i) Yaroshinsky's role in attempting to obtain FDA approval of Velac (*see, e.g.*, ¶¶40, 90); (ii) Yaroshinsky's participation in the non-public ECAC Conference Call where he learned Velac would not be approved (¶¶107-109); (iii) the characterization of the ECAC Conference Call by CW6, who participated in the call and says the FDA made it clear that approval of Velac did not look likely; (iv) Yaroshinsky's immediate phone calls to his former neighbor Zak after which Zak immediately sold a lot of Connetics stock (¶¶133-134); (v) Yaroshinsky's extreme change in his position in Connetics securities, changing to extremely bearish after the conference call and trading directly in violation of the Company's ban from doing so (¶¶133-142); and (vi) Yaroshinsky was disciplined by Connetics for his insider trading (¶50). While Lead Plaintiff's § 20A claims are based upon Yaroshinsky's insider sales and illegal communications to Zak, Lead Plaintiff's scienter allegations are supported by additional specific facts not limited to Zak's or Yaroshinsky's trading.

In a variant of the argument raised by Connetics that Defendants' April 26 statements

were not misleading (*see supra* § III.B.3.b), Yaroshinsky incorrectly asserts that he "believed . . . that all material non-public information regarding the April 13 call and the transgenic mouse study had been disclosed to the market on April 26, 2005 and that there was no legal impediment to trading." Yaroshinsky MTD at 17. ***First***, the Court has already indicated that the April 26 statements were misleading. *See* 1/29 Order at 17. ***Second***, this argument ignores the fact that Connetics banned Yaroshinsky from trading in Connetics securities until May 10, 2005 – thereby telling him that he had material, non-public information. *See* ¶135. *See also* Declaration of Gerard A. Trippitilli in Support of Alexander Yaroshinsky's Motion to Dismiss and Motion to Strike, Ex. B The SEC Complaint at ¶26 ("Connetics also imposed a trading prohibition that extended to May 10, 2005 . . ., which also included Yaroshinsky."). ***Third***, Yaroshinsky ignores the facts, including his creation of a secret trading account registered in the name of his mother-in-law so as to avoid the trading ban instituted by Connetics. ¶¶135-136. ***Fourth***, Yaroshinsky offers no competing inference as to why, on April 27, he sold nearly all his Connetics shares and bought put contracts to profit from a further decline in the Company's stock price. ¶137.

4. Defendants' Additional Arguments

Defendants argue that the Complaint should be dismissed because Lead Plaintiff does not state a independent violation of the Exchange Act aside from claims under § 20A. Yaroshinsky MTD at 19. However, the law is clear that "§ 10(b) and Rule 10b-5 are violated when a corporate insider trades in the securities of his corporation on the basis of material, nonpublic information. Trading on such information qualifies as a 'deceptive device' under § 10(b) . . . ." *O'Hagan*, 521 U.S. at 651-652. Here, Yaroshinsky and Zak's illegal insider trading establishes the violation of Section 10(b).

Defendants assert that Lead Plaintiff seeks only compensatory damages and/or rescission, which is not available under § 20A and therefore the claims against Yaroshinsky and Zak should be dismissed. Yaroshinsky MTD at 19. In truth, however, Lead Plaintiff seeks all appropriate relief, including disgorgement of illegally gained proceeds from insider selling.

IV. CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss should be denied in their

entirety. In the event the Court finds deficiencies in the Complaint, Lead Plaintiff respectfully requests leave to amend. Leave to amend is freely given unless the Complaint could not possibly be cured by the allegation of other facts. "Adherence to these principles is especially important in the context of the PSLRA . . . . In this technical and demanding corner of the law, the drafting of a cognizable complaint can be a matter of trial and error." *Eminence Capital, L.L.C. v. Aspeon, Inc*., 316 F.3d 1048, 1052 (9th Cir. 2003) (*per curiam*).

Dated: June 20, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Kristina L. Sousek, do hereby certify that on this 20th day of June, 2008, a true and correct copy of the foregoing

LEAD PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS THE SECOND AMENDED CONSOLIDATED COMPLAINT

was filed electronically. Those attorneys who are registered with the Electronic Case Filing ("ECF") System may access this filing through the Court's system, and notice of this filing will be sent to the parties by operation of the Court's ECF System. Attorneys not registered with the Court's ECF system will be duly and properly served via Federal Express or U.S. Mail (as indicated on the attached Service List), in accordance with the Federal Rules of Civil Procedure and the Court's Local Rules.

I further declare that, pursuant to Civil L.R. 23-2, on this date I served copies of the above documents on the Securities Class Action Clearinghouse by electronic mail through the following electronic mail address provided by the Securities Class Action Clearinghouse:

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